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The Role of Litigation in the Fight Against Prescription Drug Abuse

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SYMPOSIUM*

THE ROLE OF LITIGATION IN THE FIGHT AGAINST PRESCRIPTION DRUG ABUSE

*Richard C. Ausness**

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INTRODUCTION

OxyContin, a prescription pain reliever, was developed by the Purdue Pharma pharmaceutical company ("Purdue") and was marketed by that company in conjunction with Abbott Laboratories ("Abbott").¹ Its active ingredient is oxycodone hydrochloride, a synthetic opioid that was developed in 1916.² Oxycodone is found in other analgesic products such as Percocet, Percodan, and Tylox.³ OxyContin is designed to control moderate to severe chronic pain.⁴ Most oxycodone-based products provide pain relief for only four to six hours.⁵ However, OxyContin has a patented time-release feature that allows oxycodone to be released over a twelve hour period, which reduces the need for repeated dosing.⁶ Because of this time-release feature, OxyContin typically contains a larger dose of oxycodone than other competing pain relievers.⁷

¹ Purdue Pharma entered into a promotion agreement with Abbott Laboratories. See *Howland v. Purdue Pharma L.P.*, 821 N.E.2d 141, 143 (Ohio 2004). This agreement provided that the two companies would both promote OxyContin and that Purdue would pay Abbott a commission on net sales of the drug. *Id.*

² See Paul D. Frederickson, *Criminal Marketing: Corporate and Managerial Liability in the Prescription Drug Industry*, 22 *MIDWEST L.J.* 115, 132 (2008). The term "opioids" refers to a group of chemicals related to opium, an analgesic, euphoric, and narcotic substance derived from the poppy plant. See Scott Burris et al., *Stopping an Invisible Epidemic: Legal Issues in the Provision of Naloxone to Prevent Opioid Overdose*, 1 *DREXEL L. REV.* 273, 281 (2009). According to one commentator, "opioid chemicals bind to the opioid receptors in the central nervous system and provide an analgesic effect because they decrease and alter the sensation of pain." Ed Woodworth, *Pharmageddon: A Statutory Solution to Curb Ohio's Prescription Abuse Problem*, 26 *J.L. & HEALTH* 103, 108 (2013).

³ David L. Robinson, Note, *Bridging the Gaps: Improved Legislation to Prohibit the Abuse of Prescription Drugs in Virginia*, 9 *APPALACHIAN J.L.* 281, 283 (2010).

⁴ See Melissa M. Ferrara, Comment, *The Disparate Treatment of Addiction-Assistance Medications and Opiate Pain Medications Under the Law: Permitting the Proliferation of Opiates and Limiting Access to Treatment*, 42 *SETON HALL L. REV.* 741, 741 (2012). In the 1980s, physicians began to prescribe opioids more aggressively to treat cancer patients. See *Foister v. Purdue Pharma, L.P.*, 295 F. Supp. 2d 693, 696 (E.D. Ky. 2003). Purdue Pharma, however, promoted the use of opioids, such as OxyContin, to treat other forms of chronic pain. See Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99 *AM. J. PUB. HEALTH* 221, 222–23 (2009).

⁵ *Id.*

⁶ Joseph B. Prater, Comment, *West Virginia's Painful Settlement: How the OxyContin Phenomenon and Unconventional Theories of Tort Liability May Make Pharmaceutical Companies Liable for Black Markets*, 100 *NW. U. L. REV.* 1409, 1413 (2006).

⁷ *Howland v. Purdue Pharma L.P.*, 821 N.E.2d 141, 143 (Ohio 2004). OxyContin currently comes in 10, 20, 40, 80, and 160 milligram strengths. See *Foister*, 295 F. Supp. 2d at 695.

Purdue began marketing OxyContin in 1996.⁸ Although in the past oxycodone and similar pain relieving drugs were usually prescribed for cancer patients, Purdue aggressively promoted OxyContin as a treatment for persons with “non-malignant” diseases such as arthritis or chronic back pain. Sales of the product grew from \$48 million in 1996 to almost \$1.1 billion in 2000,⁹ and OxyContin eventually became the most prescribed Schedule II narcotic drug in the United States.¹⁰ By 2009, physicians wrote more than six million prescriptions for OxyContin and retail sales of the drug reached \$3 billion.¹¹ Unfortunately, the popularity of OxyContin as a pain reliever also led to widespread abuse of the drug, particularly in rural areas such as Appalachia.¹² In the words of the Federal District Court for the Eastern District of Kentucky,

Such areas have become a breeding ground for OxyContin abuse because “they’re home to large populations of disabled and chronically ill people who are in need of pain relief; they’re marked by high unemployment and a lack of economic opportunity; they’re remote, far from the network of Interstates and metropolises through which heroin and cocaine travel; and they’re areas where prescription drugs have been abused—though in much smaller numbers—in the past.”¹³

Drug abusers are able to defeat OxyContin’s time-release coating by crushing the pill and snorting it or by administering it intravenously.¹⁴ They are able to obtain large amounts of OxyContin in various ways. “Pill mills” are one source of illicit drugs. A pill mill is a physician, pain management clinic, or pharmacy that prescribes or dispenses prescription narcotics inappropriately or for non-medical purposes.¹⁵ Pill mills are characterized by payment in cash only, no physical exams, treatment with pain medication only, and large crowds

⁸ The FDA approved OxyContin on December 12, 1995. See Ferrara, *supra* note 4, at 749.

⁹ Van Zee, *supra* note 4, at 221.

¹⁰ Diane E. Hoffmann, *Treating Pain v. Reducing Drug Diversion and Abuse: Recalibrating the Balance in Our Drug Control Laws and Policies*, 1 ST. LOUIS U. J. HEALTH L. & POL’Y 231, 273 (2008).

¹¹ See Ferrara, *supra* note 4, at 741–42.

¹² See Robinson, *supra* note 3, at 284.

¹³ See Foister v. Purdue Pharma, L.P., 295 F. Supp. 2d 693, 696 (E.D. Ky. 2003) (quoting Paul Tough, *The Alchemy of OxyContin*, N.Y. TIMES (July 29, 2001), <http://www.nytimes.com/2001/07/29/magazine/the-alchemy-of-oxycontin.html?src=pm&pagewanted=1&pagewanted=all>).

¹⁴ Sheryl Calabro, *Breaking the Shield of the Learned Intermediary Doctrine: Placing the Blame Where It Belongs*, 25 CARDOZO L. REV. 2241, 2245 (2004).

¹⁵ Woodworth, *supra* note 2, at 113–14.

waiting to be seen.¹⁶ Another technique, known as “doctor shopping,” involves receiving treatment from more than one physician concurrently.¹⁷ Drug abusers will often visit multiple physicians in order to obtain multiple prescriptions of their preferred drug.¹⁸ Some drug abusers also engage in “pharmacy diversion,” which occurs when employees forge prescriptions or simply remove OxyContin from pharmacy shelves.¹⁹ Another form of pharmacy diversion involves robberies and burglaries by criminals seeking to obtain prescription drugs.²⁰

The drug abuse problems described above have prompted a number of responses by both drug users (and abusers) and by various federal and state government agencies. Many of these responses have involved civil litigation against Purdue and others, including individual lawsuits, class actions and *parens patriae* suits by state officials. On the whole, individual lawsuits and class actions have not been very successful. *Parens patriae* suits brought by state attorneys general against the manufacturer of OxyContin have fared better and have led to some fairly generous settlements for the states involved. On the other hand, criminal prosecutions have generally been more successful in the sense that the government has achieved a high conviction rate in these cases. However, it is less certain whether criminal prosecutions have actually had much impact on the underlying drug abuse problem. This Article concludes that litigation, both civil and criminal, is a valuable tool in the war against prescription drug abuse. However, it is only part of the solution. Other measures, such as prescription monitoring programs, anti-doctor shopping laws, and unused prescription drug collection programs, also have an important role to play.

Part I examines the impressive array of liability theories that individual litigants have relied upon in their lawsuits against Purdue. These theories include: negligence; strict products liability, including design defect and inadequate warning claims; breach of the implied warranty of merchantability; violation of state consumer protection statutes; negligent marketing; fraudulent misrepresentation; civil conspiracy; and “malicious conduct.” Purdue, in turn, has pursued an aggressive “no settlement” policy and has chosen to spend a considerable amount of money on legal fees instead of providing compensation to individuals with addiction or other health problems.²¹ The company managed

¹⁶ Ashley Dutko, *Florida's Fight Against Prescription Drug Abuse: Prescription Drug Monitoring Program*, 34 NOVA L. REV. 739, 744 (2010).

¹⁷ See Amy L. Cadwell, Note, *In the War on Prescription Drug Abuse, E-Pharmacies Are Making Doctor Shopping Irrelevant*, 7 HOUS. J. HEALTH L. & POL'Y 85, 89–90 (2006).

¹⁸ See Robinson, *supra* note 3, at 289.

¹⁹ See Prater, *supra* note 6, at 1416.

²⁰ See Ken Lammers, Jr., *Rise of the Pills*, 15 D.C. L. REV. 91, 95 (2011).

²¹ See Frederickson, *supra* note 2, at 134.

to win most of these cases at the summary judgment level by claiming no causation, misuse, wrongful conduct, or expiration of the statute of limitations.

Part II considers the history of class actions in this area and concludes that in many instances the courts have denied class certification because representatives of the putative class have been unable to satisfy the requirements of Rule 23(a). Commonality has been the most troublesome roadblock to class certification, but courts have also denied class certification for failure to satisfy other requirements such as numerosity, typicality, and adequacy.

Part III discusses *parens patriae* lawsuits. These are lawsuits brought against Purdue by state attorneys general to protect or vindicate the state's "quasi-sovereign" interests in the health, safety, or welfare of its citizens.²² Part III concludes that these lawsuits have been more successful than other forms of civil litigation for various reasons. In the first place, state officials can muster more effective legal resources than individual litigants. Secondly, governmental litigants are not subject to the conduct-based defenses that have been invoked to defeat individual plaintiffs in product misuse cases.

Part IV examines criminal prosecutions of Purdue, physicians who overprescribe opioid drugs, and pharmacists who supply these products to drug abusers. Finally, Part V assesses the effectiveness of civil and criminal litigation as a tactic in the fight against drug abuse, particularly as it relates to OxyContin use. After evaluating the various categories of civil litigation, the Article examines other approaches that are currently employed to combat drug abuse or might be employed in the future. One such approach is criminal prosecution of opioid producers, physicians who overprescribe these drugs, and pharmacies that operate as "pill mills" to supply narcotic products to drug abusers. Another strategy is to establish an effective monitoring program to oversee opioid use by residents of a state. Another initiative would be the enactment of anti-doctor-shopping laws to discourage drug abusers from obtaining drugs in this manner. A final approach would be to implement "take back" programs to provide for the safe disposal of unwanted prescription drugs.

I. INDIVIDUAL LAWSUITS

Private civil litigation includes individual lawsuits and class actions, but it excludes *qui tam* actions brought by private individuals on behalf of the government.²³ This latter category will not be discussed because they involve

²² See Donald G. Gifford, *Impersonating the Legislature: State Attorneys General and the Parens Patriae Product Litigation*, 49 B.C. L. REV. 913, 931 (2008).

²³ Most of the damage awards collected by the federal government from drug companies have resulted from *qui tam* actions brought by private parties on behalf of the government. See Fredrickson, *supra* note 2, at 124. These lawsuits are authorized by the False Claims Act, 31

purely economic claims rather than personal injury claims. A number of individuals have brought suit against Purdue, contending that the company is responsible for the consequences of their drug abuse and addiction.²⁴ However, Purdue has won most of these cases on summary judgment by successfully raising issues such as lack of causation,²⁵ misuse,²⁶ wrongful conduct,²⁷ or running of the statute of limitations.²⁸

A. *Liability Theories*

Plaintiffs in individual lawsuits have invoked a variety of conventional and novel liability theories to support their claims. These include negligence,²⁹ strict products liability,³⁰ failure to warn,³¹ breach of implied warranty,³²

U.S.C. §§ 3729–3733 (2000), a Civil War era statute that imposes liability on anyone who submits a false or fraudulent claim to the government for payment. *See* Richard C. Ausness, “*There’s Danger Here, Cherie!*”: *Liability for the Promotion and Marketing of Drugs and Medical Devices for Off-Label Uses*, 73 BROOK. L. REV. 1253, 1275 (2008). These individuals, known as relators, may be private citizens, government employees, employees of private contractors, employees, or ex-employees of the defendant in question or even competitors of the defendant. *See* William E. Kovacic, *Whistleblower Bounty Lawsuit as Monitoring Devices in Governing Contracting*, 29 LOY. L.A. L. REV. 1799, 1812 (1996). If the lawsuit is successful, the relator receives a share of the recovery. *See* Christopher C. Frieden, Comment, *Protecting the Government’s Interests: Qui Tam Actions Under the False Claims Act and the Government’s Right to Veto Settlements of Those Actions*, 47 EMORY L.J. 1041, 1053–54 (1998). There have been several *qui tam* actions brought against Purdue Pharma involving the company’s promotion of OxyContin. *See* United States *ex rel.* May v. Purdue Pharma L.P., No. 5:10-cv-01423, 2012 WL 4056720 (S.D.W. Va. 2012); United States *ex rel.* Radcliffe v. Purdue Pharma L.P., 582 F. Supp. 2d 766 (W.D. Va. 2008), *aff’d*, 600 F.3d 319 (4th Cir. 2010).

²⁴ *See* Calabro, *supra* note 14, at 2246.

²⁵ *See* Koenig v. Purdue Pharma Co., 435 F. Supp. 2d 551 (N.D. Tex. 2006); Foister v. Purdue Pharma, L.P., 295 F. Supp. 2d 693 (E.D. Ky. 2003).

²⁶ *See* Foister, 295 F. Supp. 2d 693; Labzda v. Purdue Pharma L.P., 292 F. Supp. 2d 1346 (S.D. Fla. 2003).

²⁷ *See* Foister, 295 F. Supp. 2d 693; Price v. Purdue Pharma Co., 920 So. 2d 479 (Miss. 2006).

²⁸ *See* Freund v. Purdue Pharma Co., No. 04-C-611, 2006 WL 482382 (E.D. Wis. 2006); Franz v. Purdue Pharma Co., No. 05-CV-201-PB, 2006 WL 455998 (D.N.H. 2006); Bayless v. Purdue Frederick Co., Inc., 52 Conn. L. Rptr. 771 (Conn. Super. Ct. 2011).

²⁹ *See* Franz, 2006 WL 455998; Price v. Purdue Pharma Co., 920 So. 2d 479 (Miss. 2006).

³⁰ *See* Franz, 2006 WL 455998; McCauley v. Purdue Pharma, L.P., 331 F. Supp. 2d 449 (W.D. Va. 2004); Price, 920 So. 2d 479.

³¹ *See* Koenig v. Purdue Pharma Co., 435 F. Supp. 2d 551 (N.D. Tex. 2006); Freund, 2006 WL 482382; Franz, 2006 WL 455998; McCauley, 331 F. Supp. 2d 449; Foister, 295 F. Supp. 2d 693.

³² *See* Freund, 2006 WL 482382; Franz, 2006 WL 455998.

violation of state consumer protection statutes,³³ negligent marketing,³⁴ fraudulent misrepresentation,³⁵ civil conspiracy³⁶ and “malicious conduct.”³⁷ Some of these theories have not been discussed in court opinions because the cases were dismissed on other grounds. Nevertheless, each of these liability theories will be examined in the context of OxyContin litigation.

1. Negligence

Although several plaintiffs have included negligence counts in their complaints,³⁸ in each case, the court granted the defendant’s motion for summary judgment without discussing the merits of the respective negligence claims. Presumably, however, these claims could have been based either on the inadequacy of the drug’s time-release coating or on overpromotion of the drug by Purdue.

2. Strict Products Liability (Defective Design)

In three cases, plaintiffs brought strict products liability claims against Purdue.³⁹ In order to prevail under strict products liability, a plaintiff must prove that the product is defective in some way. In general, a product may be defectively manufactured, defectively designed, or defective because of inadequate warnings or instructions.⁴⁰ There was no evidence in any of these cases that OxyContin was defectively manufactured, and failure to warn claims are discussed below. This leaves defective design. The only bases for a defective design claim would be (1) the amount of oxycodone in the larger dose pills was excessive, (2) the manufacturer failed to add an antagonist substance to the pills, or (3) the time-release mechanism was defective because it was not tamper proof.

The first type of claim would probably fail because the high dose of oxycodone, coupled with the time-release feature, provides pain relief for a longer period than other pain medication. This therapeutic benefit would arguably justify the increased risk of abuse. The second defect claim is

³³ See *Williams v. Purdue Pharma Co.*, 297 F. Supp. 2d 171 (D.D.C. 2003); *Labzda v. Purdue Pharma L.P.*, 292 F. Supp. 2d 1346 (S.D. Fla. 2003); *Bayless*, 2011 WL 6117927.

³⁴ See *Koenig*, 435 F. Supp. 2d 551; *Freund*, 2006 WL 482382; *McCauley*, 331 F. Supp. 2d 449; *Williams*, 297 F. Supp. 2d 171; *Labzda*, 292 F. Supp. 2d 1346.

³⁵ See *Freund*, 2006 WL 482382; *Franz*, 2006 WL 455998; *Price*, 920 So. 2d 479.

³⁶ See *Koenig*, 435 F. Supp. 2d 551; *Franz*, 2006 WL 455998.

³⁷ See *Freund*, 2006 WL 482382; *Price*, 920 So. 2d 479.

³⁸ See *Franz*, 2006 WL 455998; *Price*, 920 So. 2d 479.

³⁹ See *Franz*, 2006 WL 455998; *McCauley*, 331 F. Supp. 2d 449; *Price*, 920 So. 2d 479.

⁴⁰ See RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 (1998).

stronger: namely that Purdue's failure to add an antagonistic drug to OxyContin might constitute a design defect.⁴¹ Antagonistic formulations can help to protect against drug overdoses by suppressing the euphoric effects that are otherwise associated with opioid use.⁴² The producers of other opioid drugs have apparently added antagonists to their products without seriously impairing the analgesic effects of their products. Purdue's failure to do so arguably constitutes a design defect. Finally, plaintiffs can maintain that OxyContin is defective because its patented time-release mechanism can be easily bypassed.⁴³ However, even if this does constitute a design defect, Purdue could raise a misuse or alteration defense to such a claim, at least when brought by a drug abuser.⁴⁴

3. Strict Products Liability (Failure to Warn)

Although plaintiffs brought failure to warn claims in a number of cases,⁴⁵ *Foister v. Purdue Pharma, L.P.*⁴⁶ was the only case that addressed the merits of such a claim. The plaintiffs in that case alleged that Purdue failed to warn them about the addictive nature of OxyContin.⁴⁷ The court determined that comment *k* to the Restatement (Second) of Torts § 402A was applicable.⁴⁸ This provision declared that an "unavoidably unsafe" product would not be subject to strict liability as long as the manufacturer provided an adequate warning about the product's inherent dangers.⁴⁹ The court reviewed the

⁴¹ See *Harris v. Purdue Pharma, L.P.*, 218 F.R.D. 590, 592 (S.D. Ohio 2003); *Wethington v. Purdue Pharma*, 218 F.R.D. 577, 586 (S.D. Ohio 2003); *Howland v. Purdue Pharma L.P.*, 821 N.E.2d 141, 144 (Ohio 2004).

⁴² See *Harris*, 218 F.R.D. at 592; *Wethington*, 218 F.R.D. at 586; *Howland*, 821 N.E.2d at 144.

⁴³ See *Prater*, *supra* note 6, at 1419.

⁴⁴ See *Labzda v. Purdue Pharma L.P.*, 292 F. Supp. 2d 1346, 1356 (S.D. Fla. 2003).

⁴⁵ See *Koenig v. Purdue Pharma Co.*, 435 F. Supp. 2d 551 (N.D. Tex. 2006); *Freund v. Purdue Pharma Co.*, No. 04-C-611, 2006 WL 482382 (E.D. Wis. 2006); *Franz v. Purdue Pharma Co.*, No. 05-CV-201-PB, 2006 WL 455998 (D.N.H. 2006); *McCauley v. Purdue Pharma L.P.*, 331 F. Supp. 2d 449 (W.D. Va. 2004); *Foister v. Purdue Pharma, L.P.*, 295 F. Supp. 2d 693 (E.D. Ky. 2003).

⁴⁶ *Foister*, 295 F. Supp. 2d 693.

⁴⁷ *Id.* at 705.

⁴⁸ *Id.*

⁴⁹ See Richard C. Ausness, *Unavoidably Unsafe Products and Strict Products Liability: What Liability Rule Should be Applied to the Sellers of Pharmaceutical Products?*, 78 KY. L.J. 705, 712-19 (1989-90). Unlike § 402A, the Products Liability Restatement does not contain a provision similar to comment *k*. However, it does have a separate provision that addresses the liability of drug and medical device manufacturers. See RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6 (1998).

language of the package insert and observed that it explicitly warned that chewing or crushing OxyContin pills could release a potentially toxic dose of oxycodone.⁵⁰ The insert also clearly warned that OxyContin could be addictive and was a “common target for both drug abusers and drug addicts.”⁵¹ On the basis of this evidence, the court concluded that the warning provided on the package insert was adequate to satisfy the requirements of comment *k*.⁵²

The *Foister* court also held that Kentucky would probably adopt the learned intermediary rule.⁵³ This rule provides that the manufacturer of a prescription drug is not required to warn the ultimate user or consumer, but may satisfy its duty to warn by communicating information about a drug’s inherent risks to the prescribing physician.⁵⁴ The physician, in turn, is expected to act as a “learned intermediary” between the manufacturer and the patient.⁵⁵ Because the package insert warnings were adequate and were communicated to the plaintiffs’ physicians, the court concluded that Purdue had fully satisfied its duty to warn.⁵⁶

4. Breach of Implied Warranty

Several plaintiffs unsuccessfully sought to recover against Purdue for breach of the implied warranty of merchantability.⁵⁷ In *Freund v. Purdue Pharma Co.*,⁵⁸ the court apparently granted the defendant’s motion for summary judgment because it concluded that the applicable statute of limitations had run.⁵⁹ The plaintiff in *Franz v. Purdue Pharma Co.*⁶⁰ also sued

⁵⁰ *Foister*, 295 F. Supp. 2d at 703.

⁵¹ *Id.* at 707.

⁵² *Id.* at 705.

⁵³ *Id.* at 706.

⁵⁴ See Lloyd C. Chatfield, Note, *Medical Implant Litigation and Failure to Warn: A New Extension for the Learned Intermediary Rule?*, 82 KY. L.J. 575 (1994); Yonni D. Fushman, Comment, *Perez v. Wyeth Labs., Inc.: Toward Creating a Direct-to-Consumer Advertisement Exception to the Learned Intermediary Doctrine*, 80 B.U. L. REV. 1161, 1162 (2000).

⁵⁵ See Richard C. Ausness, *Will More Aggressive Marketing Practices Lead to Greater Tort Liability for Prescription Drug Manufacturers?*, 37 WAKE FOREST L. REV. 97, 107 (2002).

⁵⁶ *Foister*, 295 F. Supp. 2d at 708.

⁵⁷ See *Freund v. Purdue Pharma Co.*, No. 04-C-611, 2006 WL 482382 (E.D. Wis. 2006); *Franz v. Purdue Pharma Co.*, No. 05-CV-201-PB, 2006 WL 455998 (D.N.H. 2006).

⁵⁸ *Freund*, 2006 WL 482382.

⁵⁹ *Id.* at *1. The court observed that although the warranty claim was not subject to the two year statute of limitations, it accepted the defendants’ uncontested assertion that the claim could not survive under Wisconsin law. *Id.* at *2 n.2. The court did not disclose the basis for this assertion so it may not have involved the statute of limitations.

⁶⁰ *Franz*, 2006 WL 455998.

for breach of the implied warranty of merchantability.⁶¹ The court dismissed most of the plaintiff's other claims because the two-year statute of limitations had run.⁶² However, the breach of warranty claim was not time barred because it was subject to a four-year statute of limitations.⁶³ Nevertheless, the court dismissed the warranty claim as well because the plaintiff failed to allege that she gave notice of her claim to the defendants, as required by the Uniform Commercial Code,⁶⁴ before filing her lawsuit.⁶⁵

5. Violation of State Consumer Protection Statutes

A number of states have enacted consumer protection laws.⁶⁶ In some cases, plaintiffs have sought to rely on these statutes, largely without success, to impose liability on Purdue. For example, in *Bayless v. Purdue Frederick Co., Inc.*,⁶⁷ the plaintiffs brought suit under the Connecticut Products Liability Act ("CPLA").⁶⁸ The drug company asserted that the CPLA claims were barred by the statute of limitations, but the court allowed the plaintiffs to proceed with their case.⁶⁹

6. Negligent Marketing

A number of plaintiffs have brought damage claims against Purdue on the basis of negligent marketing.⁷⁰ As its name implies, this relatively new liability theory, which is often referred to as "overpromotion," is based on negligence principles rather than principles of strict products liability.⁷¹ If a court concludes that a manufacturer or other seller has engaged in negligent marketing, it may impose liability for harm caused by a product even though

⁶¹ *Id.* at *1.

⁶² *Id.* at *3.

⁶³ *Id.* at *3 n.5.

⁶⁴ See N.H. REV. STAT. ANN. § 382-A:2-607(3)(a) (2014).

⁶⁵ *Franz*, 2006 WL 482382, at *3.

⁶⁶ See generally MARSHALL S. SHAPO, SHAPO ON THE LAW OF PRODUCTS LIABILITY § 7.06 (2012).

⁶⁷ *Bayless v. Purdue Frederick Co., Inc.*, 52 Conn. L. Rptr. 771 (Conn. Super. Ct. 2011).

⁶⁸ CONN. GEN. STAT. § 52-577a(a) (2014).

⁶⁹ *Bayless*, 52 Conn. L. Rptr. 771.

⁷⁰ See *Koenig v. Purdue Pharma Co.*, 435 F. Supp. 2d 551, 553 (N.D. Tex. 2006); *Labzda v. Purdue Pharma L.P.*, 292 F. Supp. 2d 1346, 1349 (S.D. Fla. 2003).

⁷¹ See Andrew Jay McClurg, *The Tortious Marketing of Handguns: Strict Liability is Dead, Long Live Negligence*, 19 SETON HALL LEGIS. J. 777, 795-96 (1996).

the product is not defective.⁷² The doctrine of negligent marketing rests on the notion that product sellers should not pursue marketing strategies that increase the risk that their products will be purchased by persons who are likely to injure themselves or to injure others.⁷³ Negligent marketing claims can be based on product design, advertising or promotional activities, and distribution practices.⁷⁴

Purdue may have engaged in each of these forms of negligent marketing. First, one could argue that the OxyContin pill was designed to appeal to drug abusers. It contained much higher quantities of oxycodone than other pain medication, as much as 160 milligrams per pill. In addition, the time-release mechanism was easy to defeat, thereby allowing drug abusers to achieve a heroin-like high. The argument for negligent promotion is even stronger. It should be noted that drug companies use a variety of marketing techniques to promote their products and most of them are legitimate when not abused.⁷⁵ However, considering that the product involved was a highly dangerous Schedule II narcotic, Purdue's promotional activities may have crossed the line. For example, between 1996 and 2001, more than 5000 health care professionals attended all-expense paid conferences at various resorts where they were invited by the company to join its national speakers' program.⁷⁶ Purdue also funded more than 20,000 educational programs, thereby influencing the prescribing of OxyContin in the United States.⁷⁷ In addition, Purdue promoted OxyContin among primary care physicians in an effort to encourage them to prescribe opioids more frequently.⁷⁸ Furthermore, it encouraged its sales representatives to promote OxyContin aggressively and even provided them with free starter coupons to give to doctors for eventual distribution to their patients.⁷⁹ Finally, in an effort to increase the use of OxyContin to treat non-cancer related chronic pain, the company in its

⁷² See Ausness, *supra* note 55, at 123.

⁷³ See Richard C. Ausness, *Tort Liability for the Sale of Non-Defective Products: An Analysis and Critique of the Concept of Negligent Marketing*, 53 S.C. L. REV. 907, 912 (2002).

⁷⁴ See McClurg, *supra* note 71, at 806–18.

⁷⁵ See Timothy Stoltzfus Jost, *Oversight of Marketing Relationships Between Physicians and the Drug and Device Industry*, 36 AM. J.L. & MED. 326, 332–34 (2010) (describing some of these practices); Marshall B. Kapp, *Drug Companies, Dollars, and the Shaping of American Medical Practice*, 29 S. ILL. U. L.J. 237, 247–61 (2005).

⁷⁶ See Van Zee, *supra* note 4, at 221.

⁷⁷ *Id.* at 225.

⁷⁸ *Id.* at 222.

⁷⁹ *Id.*

marketing and promotion activities downplayed the risk of addiction from long-term opioid use.⁸⁰

In *Labzda v. Purdue Pharma L.P.*,⁸¹ the parents of a deceased drug abuser relied on the concept of negligent marketing, claiming that the defendants knew that a particular physician was over-prescribing OxyContin to his patients, but they “did not attempt to curtail the inappropriate prescriptions, ignoring the potential for abuse of their product.”⁸² However, the court concluded that the product was not defective and the manufacturer provided adequate warnings to the medical community.⁸³ In addition, the court determined that there was no special relationship between the defendants and the decedent that would impose a duty on the drug company to control the overprescribing of OxyContin.⁸⁴ Finally, the court ruled that neither state nor federal law imposed a duty on the defendants to report the physician to the authorities.⁸⁵

7. Fraudulent Misrepresentation

Purdue has been accused of training its sales representatives to “falsely promote the opioid analgesic as less likely than other pain medications to cause abuse, addiction, tolerance, and withdrawal.”⁸⁶ In addition, “healthcare providers were deliberately misinformed that the extended-release formulation rendered oxycodone extraction more difficult and therefore decreased the potential for abuse, and that lack of euphoria rendered it less addictive than immediate-release opiates or even morphine.”⁸⁷ This conduct, if true, fits the description of intentional or fraudulent misrepresentation, and several plaintiffs have alleged as much in their pleadings.⁸⁸

According to one court, a fraudulent representation claim requires proof of the following by clear and convincing evidence:

⁸⁰ *Id.* at 223. Purdue also promoted OxyContin to the general public through its website, “Partners Against Pain.” See Prater, *supra* note 6, at 1430 n.172.

⁸¹ *Labzda v. Purdue Pharma L.P.*, 292 F. Supp. 2d 1346 (S.D. Fla. 2003).

⁸² *Id.* at 1348–49.

⁸³ *Id.* at 1353.

⁸⁴ *Id.* at 1355.

⁸⁵ *Id.*

⁸⁶ See Lammers, *supra* note 20, at 91 (quoting Yael Wajnne, *False Promotion of OxyContin Costs Purdue Frederick \$600 Million*, MEDSCAPE (May 11, 2007), <http://www.medscape.com/viewarticle/556381>).

⁸⁷ *Id.*

⁸⁸ See *Freund v. Purdue Pharma Co.*, No. 04-C-611, 2006 WL 482382, at *1 (E.D. Wis. 2006); *Franz v. Purdue Pharma Co.*, No. 05-CV-201-PB, 2006 WL 455998, at *1 (D.N.H. 2006); *Price v. Purdue Pharma Co.*, 920 So. 2d 479, 482 (Miss. 2006).

1) a representation; 2) which is material to the transaction at hand; 3) made falsely, with knowledge of its falsity or recklessness as to whether it is true or false; 4) with the intent of misleading another into relying on it; 5) justifiable reliance on the misrepresentation; and 6) the resulting injury was proximately caused by the reliance.⁸⁹

The statements and assurances made by Purdue's sales representatives to physicians arguably satisfy the first four elements. Whether a plaintiff could prove the fifth element would depend upon how familiar the target physician was with opioids in general and OxyContin in particular. The sixth element might also be a problem if the plaintiff had independent knowledge of the addictive qualities of OxyContin and consumed the drug anyway. In any event, these issues have not been litigated in the context of individual lawsuits because the three suits in which fraud was alleged were dismissed prior to trial.⁹⁰

8. Civil Conspiracy

In several cases, individual plaintiffs have accused Purdue of engaging in a civil conspiracy.⁹¹ A civil conspiracy involves a group of two or more persons acting together to achieve an unlawful objective or to achieve a lawful objective by unlawful or criminal means.⁹² The civil conspiracy claim rests on an allegation that Purdue and its partner, Abbott, engaged in a civil conspiracy to increase OxyContin's market share by misrepresenting its risks and benefits to the medical community.⁹³ However, in both cases, the plaintiffs' lawsuits were dismissed on other grounds, so their civil conspiracy claims were not actually adjudicated.⁹⁴

⁸⁹ See *Goldstein v. Phillip Morris, Inc.*, 854 A.2d 585, 591 (Pa. Super. Ct. 2004) (citing *Debbs v. Chrysler Corp.*, 810 A.2d 137, 15 (Pa. Super. Ct. 2002)).

⁹⁰ See *Freund*, 2006 WL 482382, at *1; *Franz*, 2006 WL 455998, at *1; *Price*, 920 So. 2d at 482.

⁹¹ See *Koenig v. Purdue Pharma Co.*, 435 F. Supp. 2d 551, 557 (N.D. Tex. 2006); *Franz*, 2006 WL 455998, at *1.

⁹² See *In re Personal Injury Asbestos Litig. No. 1*, 737 F. Supp. 1087, 1095 (D. N.D. 1990); *Belkow v. Celotex Corp.*, 722 F. Supp. 1547, 1550 (N.D. Ill. 1989); *Fenestra, Inc. v. Gulf Am. Land Corp.*, 141 N.W.2d 36, 48 (Mich. 1966); *Triplex Communications, Inc. v. Riley*, 900 S.W.2d 716, 719 (Tex. 1995).

⁹³ See *Koenig*, 435 F. Supp. 2d at 557; *Franz*, 2006 WL 455998, at *1.

⁹⁴ *Id.*

9. Malicious Conduct

Finally, plaintiffs in two cases accused Purdue of engaging in “malicious conduct.”⁹⁵ However, in neither case did they define what they meant by malicious conduct.⁹⁶ Nor did the plaintiffs disclose whether malicious conduct was an independent claim or whether it was made in support of a claim for punitive damages. As with so many other novel claims, the plaintiffs’ lawsuits were dismissed on other grounds so the courts never got around to deciding what might constitute malicious conduct in these cases.

B. *Defenses and Other Limitations on Liability*

Purdue won all but one of the cases surveyed. In each instance, the defendant prevailed on a motion for summary judgment, either by showing that the plaintiff had failed to prove an essential element of his or her theory of liability or by successfully invoking an affirmative defense.

1. Lack of Causation

Proving causation is a serious problem for individual plaintiffs, particularly when they have abused pain medication before their initial exposure to OxyContin.⁹⁷ The following two cases illustrate the causation problems plaintiffs may encounter in OxyContin cases. One involves cause-in-fact, while the other is more concerned with proximate cause.

In *Koenig v. Purdue Pharma Co.*,⁹⁸ the plaintiff brought suit against Abbott, which co-promoted OxyContin along with Purdue, and alleged that the drug company’s “promotional marketing campaign failed to adequately warn doctors about the addiction risks of OxyContin and affirmatively misrepresented and minimized those risks in order to increase OxyContin sales.”⁹⁹ The plaintiff also claimed that his physician prescribed OxyContin, causing him to become addicted and suffer adverse health consequences as a result.¹⁰⁰ However, the court granted the defendant’s motion for summary

⁹⁵ See *Freund*, 2006 WL 482382; *Price*, 920 So. 2d 479.

⁹⁶ However, at least one court has defined malicious conduct as “a purposeful act or conscious omission to do an act with the intent to do wrong or cause injury.” *Matthews v. State*, 825 P.2d 224, 230 (N.M. Ct. App. 1991).

⁹⁷ See *Prater*, *supra* note 6, at 1419.

⁹⁸ *Koenig*, 435 F. Supp. 2d 551.

⁹⁹ *Id.* at 553.

¹⁰⁰ *Id.*

judgment, concluding that Mr. Koenig produced no evidence of a causal connection between Abbott's co-promotion of OxyContin and his injuries.¹⁰¹

It appears that Abbott did not contact the plaintiff's physician, Dr. Danshaw, until nearly two years after the physician had begun treating Koenig with OxyContin.¹⁰² Consequently, the court determined that Abbott's promotional activities did not cause Dr. Danshaw to prescribe OxyContin and, therefore, did not cause the plaintiff's injuries.¹⁰³ Lack of causation also resulted in the dismissal of the plaintiff's failure to warn claim against Purdue.¹⁰⁴ Dr. Danshaw testified that he was aware of the addiction risks associated with the use of opioids like OxyContin and chose to prescribe it anyway.¹⁰⁵ Therefore, even if Purdue's warning was inadequate, this deficiency would not have influenced Dr. Danshaw's decision to prescribe OxyContin to the plaintiff.¹⁰⁶

Another federal district court held in favor of Purdue on proximate cause grounds. In *Foister v. Purdue Pharma, L.P.*,¹⁰⁷ seven plaintiffs brought suit against Purdue and alleged that the company failed to adequately warn about the risk of addiction from OxyContin.¹⁰⁸ However, the court concluded that the plaintiffs' conduct, which included intentional alteration of the product and ignoring dosing instructions, was a superseding cause that severed any causal connection between OxyContin and their injuries.¹⁰⁹

2. Misuse

Misuse, in the sense of putting a product to a clearly improper use, will bar recovery of a product liability claim in most states.¹¹⁰ Purdue has been successful in asserting this defense to defeat claims against it by drug abusers.¹¹¹ For example, in *Labzda v. Purdue Pharma L.P.*,¹¹² the plaintiffs alleged that their adult son, Michael Labzda, died as the result of an overdose

¹⁰¹ *Id.*

¹⁰² *Id.* at 554.

¹⁰³ *Id.*

¹⁰⁴ *Id.* at 555.

¹⁰⁵ *Id.*

¹⁰⁶ *Id.* at 555–56.

¹⁰⁷ *Foister v. Purdue Pharma L.P.*, 295 F. Supp.2d 693 (E.D. Ky. 2003).

¹⁰⁸ *Id.* at 705.

¹⁰⁹ *Id.* at 703.

¹¹⁰ See generally DAVID G. OWEN, PRODUCTS LIABILITY LAW § 13.5 (2d ed. 2008).

¹¹¹ See *Foister*, 295 F. Supp. 2d 693; *Labzda v. Purdue Pharma L.P.*, 292 F. Supp. 2d 1346 (S.D. Fla. 2003).

¹¹² *Labzda*, 292 F. Supp. 2d 1346.

of OxyContin prescribed by Dr. Deonarine.¹¹³ The plaintiffs contended that the drug manufacturer knew that Dr. Deonarine overprescribed OxyContin to many of his patients, including their son, but did nothing to curtail this practice.¹¹⁴ The defendant argued that Michael Labzda's intentional misuse of OxyContin was sufficient to bar recovery.¹¹⁵ The court declared that the decedent had a long history of drug abuse, dating from his days in high school.¹¹⁶ On the night of his death, he drank 14 beers and at least two rum and Cokes.¹¹⁷ In addition, he shared five marijuana cigarettes, took three tablets of the strongest strength of Xanax and crushed and snorted one and a half to two 80 milligram tablets of OxyContin.¹¹⁸ Based on this evidence, the court rejected the plaintiffs' argument that the doctrine of comparative negligence should permit at least some recovery.¹¹⁹ Instead, the court relied on *Bruner v. Anheuser-Busch, Inc.*¹²⁰ to conclude that the decedent's behavior was not merely negligent, but constituted product misuse and, therefore, barred any recovery.¹²¹

3. Wrongful Conduct

Some states also have a rule that "wrongful conduct" will prevent a plaintiff who has engaged in illegal conduct from recovering for harm caused by such actions.¹²² This doctrine has been successfully invoked by Purdue in several cases.¹²³ For example, *Price v. Purdue Pharma Co.*¹²⁴ affirmed a summary judgment in favor of the drug company because it concluded that the plaintiff had engaged in illegal and wrongful conduct.¹²⁵ In that case, the plaintiff sued various doctors, pharmacies, and drug companies for injuries he

¹¹³ *Id.* at 1348. Dr. Deonarine was subsequently prosecuted by the State of Florida for drug trafficking. *See Deonarine v. State*, 967 So. 2d 333, 335–36 (Fla. D.C.A. 2007).

¹¹⁴ *Labzda*, 292 F. Supp. 2d at 1348–49.

¹¹⁵ *Id.* at 1356.

¹¹⁶ *Id.* at 1350.

¹¹⁷ *Id.*

¹¹⁸ *Id.*

¹¹⁹ *Id.* at 1356.

¹²⁰ *Bruner v. Anheuser-Busch, Inc.*, 153 F. Supp. 2d 1358 (S.D. Fla. 2001), *aff'd*, 31 Fed. App'x 932 (11th Cir. 2002).

¹²¹ *Labzda*, 292 F. Supp. 2d at 1356.

¹²² *See, e.g., Pappas v. Clark*, 494 N.W.2d 245 (Iowa Ct. App. 1992); *Orzel v. Scott Drug Co.*, 537 N.W.2d 208 (Mich. 1995).

¹²³ *See Foister v. Purdue Pharma, L.P.*, 295 F. Supp. 2d 693, 704–05 (E.D. Ky. 2003); *Price v. Purdue Pharma Co.*, 920 So. 2d 479, 484–86 (Miss. 2006).

¹²⁴ *Price*, 920 So. 2d 479.

¹²⁵ *Id.* at 481.

allegedly sustained from ingesting OxyContin.¹²⁶ The evidence showed that between November 1999 and October 2000, the plaintiff visited ten different physicians from ten different clinics in two cities and used seven pharmacies in three cities in order to obtain enough OxyContin to satisfy his drug habit.¹²⁷ Applying the maxim that “[n]o Court will lend its aid to a man who founds his cause of action upon an immoral or an illegal act,”¹²⁸ the court declared that the plaintiff’s “doctor shopping” was illegal because it violated federal drug restrictions.¹²⁹ According to the court, the plaintiff’s violation of the law was “not merely a condition, but instead [it was] an integral and essential part of his case and *the* contributing cause of his alleged injury.”¹³⁰ Consequently, the court held that the plaintiff’s claims were barred.¹³¹

4. Statute of Limitations

Finally, Purdue has sought to defeat claims against it by OxyContin users by contending that the claims are barred by the statute of limitations.¹³² In each case, the plaintiffs argued that the court should apply the discovery rule to toll the statute of limitations.¹³³ The first of these cases was *Franz v. Purdue Pharma Co.*,¹³⁴ an unreported case from a New Hampshire federal district court. The plaintiff’s physician first prescribed OxyContin in 1996 to alleviate a painful condition.¹³⁵ In October 2000, the plaintiff was hospitalized for addiction and withdrawal symptoms.¹³⁶ In April 2004, she filed suit against Purdue and Abbott, claiming that OxyContin was defective, that the defendants made fraudulent misrepresentations about its efficacy, and that they failed to

¹²⁶ *Id.*

¹²⁷ *Id.* at 482.

¹²⁸ *Id.* at 484 (quoting *Morrissey v. Bologna*, 123 So. 2d 537, 545 (Miss. 1960)).

¹²⁹ *Price*, 920 So. 2d. at 484.

¹³⁰ *Id.* at 485.

¹³¹ *Id.* at 486.

¹³² See *Franz v. Purdue Pharma Co.*, No. 05-CV-201-PB, 2006 WL 455998 (D.N.H. 2006); *Freund v. Purdue Pharma Co.*, No. 04-C-611, 2006 WL 482382 (E.D. Wis. 2006); *Bayless v. Purdue Frederick Co., Inc.*, 52 Conn. L. Rptr. 771 (Conn. Super. Ct. 2011).

¹³³ Ordinarily, the statute of limitations starts to run at the time of the plaintiff’s injury. See OWEN, *supra* note 110, § 14.5. However, the discovery rule provides that a cause of action does not accrue until the plaintiff discovers, or in the exercise of reasonable diligence should have discovered, relevant facts about the injury. *Id.* Although the discovery rule was first applied in medical malpractice cases, it is now applicable to products liability cases. *Id.*

¹³⁴ *Franz*, 2006 WL 455998.

¹³⁵ *Id.* at *1.

¹³⁶ *Id.* at *2.

provide adequate instructions and warnings.¹³⁷ In response, the defendants maintained that the applicable two-year statute of limitations began to run in October 2000 when the plaintiff was hospitalized for addiction, and expired in October 2002 more than a year before she filed her complaint against them.¹³⁸ On the other hand, the plaintiff contended that she did not become aware of the defendants' wrongdoing at that time because when her physician first prescribed OxyContin, he assured the plaintiff that the drug was not addictive.¹³⁹ According to the plaintiff, it was not until April 2003, when she heard about problems with OxyContin on a television program, that she first became aware that the defendants might be responsible for her drug addiction problem.¹⁴⁰

Citing *Curry v. A.H. Robins Co.*,¹⁴¹ the court acknowledged that the discovery rule did not require that a person have actual knowledge of the defendant's wrongful conduct; instead, it provided that the statute of limitations would start to run when "a reasonable person would have realized [that her injuries] might have been the result of actionable conduct."¹⁴² Applying this test to the plaintiff's case, the court in *Franz* concluded that even if the plaintiff did not have actual knowledge of the connection between OxyContin use and her addiction until April 2003, she should have realized as early as October 2000 that her injuries might have been caused by the defendants' conduct when she was admitted to the hospital for OxyContin related illness.¹⁴³ Accordingly, the court granted the defendants' motion for summary judgment.¹⁴⁴

*Freund v. Purdue Pharma Co.*¹⁴⁵ was also concerned with whether the discovery doctrine would toll the statute of limitations in OxyContin addiction cases. The plaintiff in that case began taking OxyContin in early 2001 when it was prescribed by her physician as treatment for chronic pain.¹⁴⁶ In July of that year, the plaintiff intentionally took an overdose of OxyContin because she felt that "the best way out of addiction was to kill myself."¹⁴⁷ Eventually, she was weaned off of OxyContin and had not taken the drug since December 2002.¹⁴⁸

¹³⁷ *Id.* at *1–2.

¹³⁸ *Id.* at *2.

¹³⁹ *Id.*

¹⁴⁰ *Id.*

¹⁴¹ 775 F.2d 212, 216 (7th Cir. 1985).

¹⁴² *Franz*, 2006 WL 455998, at *2 (quoting *Curry*, 775 F.2d at 216).

¹⁴³ *Id.* at *3.

¹⁴⁴ *Id.*

¹⁴⁵ No. 04-C-611, 2006 WL 482382 (E.D. Wis. 2006).

¹⁴⁶ *Id.* at *1.

¹⁴⁷ *Id.*

¹⁴⁸ *Id.*

The plaintiff brought suit against Purdue and Abbott on October 31, 2003, alleging that the defendants' marketing campaign was misleading and failed to warn about the addiction risks of OxyContin.¹⁴⁹ The defendants moved for summary judgment, claiming that the applicable two-year statute of limitations had run.¹⁵⁰ According to the defendants, the plaintiff knew by July 2001 that she was experiencing depression and addictive symptoms and was required at that time to investigate the cause of her suffering.¹⁵¹

The court declared that it must determine when the plaintiff "*should* have known that her injury was wrongfully caused."¹⁵² The court began by stating that it must examine the spectrum of knowledge to determine the point at which the statute of limitations would begin to run.¹⁵³ At one end of the spectrum, the statute could start to run as soon as the harm itself was discovered, while at the other end the limitations period would not begin until the plaintiff learned about the specific nature of the wrongful conduct, that is, whether it was negligent, fraudulent, or something else.¹⁵⁴ Rejecting both of these extremes, the court concluded that a person knows, or reasonably should know, that an injury was wrongfully caused when he possesses "sufficient information concerning his injury and its cause to put a reasonable person on inquiry to determine whether actionable conduct is involved."¹⁵⁵ Applying this standard to the facts of the case, the court determined that the plaintiff would have had a duty by July 2001 to investigate the causes of her injury and to determine whether they may have involved wrongful conduct.¹⁵⁶ Since the plaintiff filed her lawsuit more than two years after that date, the court ruled that her claims against Purdue and Abbott were barred by the statute of limitations.¹⁵⁷

More recently, the plaintiff in *Bayless v. Purdue Frederick Co., Inc.*¹⁵⁸ survived a defendant's motion for summary judgment.¹⁵⁹ The plaintiff sought to recover under the Connecticut Products Liability Act¹⁶⁰ against Purdue for

¹⁴⁹ *Id.* at *1–2.

¹⁵⁰ *Id.* at *2.

¹⁵¹ *Id.*

¹⁵² *Id.*

¹⁵³ *Id.*

¹⁵⁴ *Id.*

¹⁵⁵ *Id.* at *3 (quoting *Knox College v. Celotex Corp.*, 430 N.E.2d 976, 980 (Ill. 1981)).

¹⁵⁶ *Id.* at *5.

¹⁵⁷ *Id.* at *7.

¹⁵⁸ 52 Conn. L. Rptr. 771 (Conn. Super. Ct. 2011).

¹⁵⁹ *Id.*

¹⁶⁰ CONN. GEN. STAT. § 52-572n(a) (2014).

injuries suffered as the result of becoming addicted to OxyContin.¹⁶¹ OxyContin was first prescribed by the plaintiff's doctor in February 1999 to treat her back pain.¹⁶² At some point, she became addicted to the drug and after March 2003 when her health insurance expired, she utilized illegal methods to obtain OxyContin.¹⁶³ In 2005, the plaintiff filed for bankruptcy and later attempted to commit suicide, was hospitalized and entered a methadone clinic for treatment of opioid addiction.¹⁶⁴ On March 6, 2009, she filed her lawsuit against Purdue.¹⁶⁵

The defendant filed a motion for summary judgment, contending that the plaintiff's claims were barred by the three-year statute of limitations.¹⁶⁶ According to the defendant, the statute of limitations began to run when the plaintiff had reason to believe that she was dependent upon or addicted to OxyContin as early as 1999, or no later than 2006 when she began to demonstrate knowledge that she was addicted to the drug.¹⁶⁷ In response, the plaintiff argued that the statute began to run, not when she discovered that she was addicted to OxyContin, but rather when she realized, or in the exercise of reasonable care should have realized, that Purdue misrepresented the addictive character of the drug and breached the warranties related to it.¹⁶⁸

The court declared that when the plaintiff in the exercise of reasonable care should have discovered "actionable harm" was generally a question of fact for the jury to decide.¹⁶⁹ In addition, the court observed that the plaintiff had alleged, *inter alia*, that Purdue had "misrepresented, marketed and promoted OxyContin as less addictive, less subject to abuse, dependence and diversion, and less likely to cause tolerance and withdrawal than other pain medication, when it knew or should have known that this was false and misleading."¹⁷⁰ In addition, the plaintiff had charged that Purdue failed to warn the plaintiff's physician and other members of the medical community about the highly addictive potential of OxyContin and had also withheld information from the FDA, health care providers, pharmacists and patients, including the plaintiff, about the health risks of the drug.¹⁷¹ In the court's view, all of these allegations

¹⁶¹ *Bayless*, 52 Conn. L. Rptr. 771. Tina's husband and son also filed derivative actions. *Id.*

¹⁶² *Id.*

¹⁶³ *Id.*

¹⁶⁴ *Id.*

¹⁶⁵ *Id.*

¹⁶⁶ *Id.*

¹⁶⁷ *Id.*

¹⁶⁸ *Id.*

¹⁶⁹ *Id.*

¹⁷⁰ *Id.*

¹⁷¹ *Id.*

raised some doubts as to when the plaintiff should have known that OxyContin was the cause of her injury.¹⁷² For this reason, the court concluded that there was a genuine issue of fact about when the plaintiff discovered or should have discovered that the defendant's conduct caused her addiction and the damages that flowed from it.¹⁷³

II. CLASS ACTIONS

There have been a number of class actions brought in recent years by OxyContin users against Purdue.¹⁷⁴ In a class action, a group of plaintiffs with similar causes of action against a particular defendant or group of defendants can sue through one or more representatives without each member of the class having to individually join in the suit.¹⁷⁵ A class action does not necessarily have to resolve the entire controversy; if necessary, a class action can be limited to particular aspects of a broader dispute.¹⁷⁶ A class action benefits plaintiffs in several ways. First, all plaintiffs have an equal opportunity to assert their claims in a class action.¹⁷⁷ Second, class members are only required to pay a pro-rated share of the litigation costs, thereby enabling them to hire more experienced attorneys to represent the class.¹⁷⁸ Finally, class action treatment reduces the potential for conflicts of interest among the plaintiffs' attorneys.¹⁷⁹ In some cases, a class action might also be advantageous to a defendant. First, a class action decreases the defendant's overall litigation costs because it does

¹⁷² *Id.*

¹⁷³ *Id.*

¹⁷⁴ See *DaWalt v. Purdue Pharma, L.P.*, 397 F.3d 392 (6th Cir. 2005); *Williams v. Purdue Pharma Co.*, 297 F. Supp. 2d 171 (D.D.C. 2003); *Campbell v. Purdue Pharma, L.P.*, No. 1:02cv00163, 2004 WL 5840206 (E.D. Mo. 2004); *Harris v. Purdue Pharma, L.P.*, 218 F.R.D. 590 (S.D. Ohio 2003); *Baker v. Purdue Pharma, L.P.*, 219 F.R.D. 111 (S.D. Va. 2003); *Wethington v. Purdue Pharma L.P.*, 218 F.R.D. 577 (S.D. Ohio 2003); *Gevedon v. Purdue Pharma*, 212 F.R.D. 333 (E.D. Ky. 2002); *Foister v. Purdue Pharma*, No. Civ.A. 01-268-DCR, 2002 WL 1008608 (E.D. Ky. 2002); *Salisbury v. Purdue Pharma, L.P.*, 166 F. Supp. 2d 546 (E.D. Ky. 2001); *Howland v. Purdue Pharma L.P.*, 821 N.E.2d 141 (Ohio 2004).

¹⁷⁵ See Case Comment, *Federal Rules of Civil Procedure—Litigation of Mass Air Crashes—District Court's Power to Certify and Conduct a Mass Accident Class Action Should Be Expanded to Conserve Judicial Time and Energy*, 29 RUTGERS L. REV. 425, 427–28 (1975).

¹⁷⁶ See 3 B. J. MOORE, FEDERAL PRACTICE ¶ 23.01 (2d ed. 1974).

¹⁷⁷ See *In re Federal Skywalk Cases*, 680 F.2d 1175, 1185 (8th Cir. 1982) (Heaney, J., dissenting).

¹⁷⁸ See Robert C. Gordon, *The Optimum Management of the Skywalks Mass Disaster Litigation by the Use of Federal Mandatory Class Action Device*, 52 UMKC L. REV. 215, 224–25 (1984).

¹⁷⁹ See Note, *Class Actions for Punitive Damages*, 81 MICH. L. REV. 1787, 1809 (1983).

not have to litigate disputes brought by multiple parties in various forums.¹⁸⁰ In addition, the use of class actions reduces the number of lawsuits involving the same parties, issues or facts, and thereby promotes judicial economy.¹⁸¹ Nevertheless, Purdue has successfully resisted class certification in OxyContin cases.

The Federal Rules of Civil Procedure set forth certain requirements that must be met in order to bring a class action suit in federal court.¹⁸² Rule 23(a) sets forth four requirements: (1) numerosity of class members, (2) commonality of legal or factual questions, (3) typicality of claims and defenses of the class representative, and (4) adequacy of class representation.¹⁸³ If these requirements are satisfied, the case must also fall within one of the categories specified in Rule 23(b).¹⁸⁴

Rule 23(a)(1) provides that the class must be so numerous that joinder is impracticable.¹⁸⁵ Rule 23(a)(2) requires that the litigation involve questions of law or fact that are common to members of the class.¹⁸⁶ Rule 23(a)(3) declares that the claims of the class members be similar, though not necessarily identical, to the claims of the representative party.¹⁸⁷ Finally, Rule 23(a)(4) requires adequacy of representation.¹⁸⁸ This involves consideration of the availability of the representative party, the expertise of the representative party's counsel, the extent of the representative party's interest and the absence of any conflicting interests among class members.¹⁸⁹ Plaintiffs bear the burden of showing that these Rule 23(a) requirements have been met.¹⁹⁰

¹⁸⁰ See Case Comment, *supra* note 175, at 451.

¹⁸¹ See *Gen. Tel. Co. of Sw. v. Falcon*, 457 U.S. 147, 155 (1982); *Harris v. Purdue Pharma, L.P.*, 218 F.R.D. 590, 592 (S.D. Ohio 2003).

¹⁸² FED. R. CIV. P. 23. Of course, plaintiffs may also choose to bring an action in state court. See, e.g., *Howland v. Purdue Pharma L.P.*, 821 N.E.2d 141 (Ohio 2004). Of course, the defendant may try to remove the case from state court to federal court on diversity ground pursuant to 28 U.S.C. § 1332. See, e.g., *DaWalt v. Purdue Pharma, L.P.*, 397 F.3d 392, 395 (6th Cir. 2005).

¹⁸³ See *Parke v. First Reliance Standard Life Ins. Co.*, 368 F.3d 999, 1004 (8th Cir. 2004).

¹⁸⁴ See Richard A. Seltzer, *Punitive Damages in Mass Tort Litigation: Addressing the Problems of Fairness, Efficiency and Control*, 52 *FORDHAM L. REV.* 37, 65-67 (1983).

¹⁸⁵ See *Payton v. Abbott Labs.*, 83 F.R.D. 382, 387 (D. Mass. 1979).

¹⁸⁶ See Note, *The Punitive Damage Class Action: A Solution to the Problem of Multiple Punishment*, 1984 *U. ILL. L. REV.* 153, 166 (1984).

¹⁸⁷ *Id.* at 167.

¹⁸⁸ *Id.*

¹⁸⁹ *Id.*

¹⁹⁰ See *Coleman v. Watt*, 40 F.3d 255, 258 (8th Cir. 1994); *Dhamer v. Bristol-Myers Squibb Co.*, 183 F.R.D. 520, 525 (N.D. Ill. 1998).

In addition, the plaintiff must satisfy one of the three requirements of Rule 23(b).¹⁹¹ A class may be certified under Rule 23(b)(1) if the plaintiff shows that separate actions by or against individual class members would risk establishing “incompatible standards of conduct for the party opposing the class,” would be dispositive of the interests or nonparty class members or would substantially impair the ability of nonparty class members to protect their interests.¹⁹² Second, a class may be certified under Rule 23(b)(2) if final relief of an injunctive nature is appropriate.¹⁹³ Finally, Rule 23(b)(3) permits a class to be certified if common questions predominate over any questions affecting only individual class members and if resolution of these questions in a class action would be a superior method for the “fair and efficient adjudication of the controversy.”¹⁹⁴

A number of OxyContin cases have been denied class certification because the class representatives were unable to satisfy one or more requirements of Rule 23(a). For example, in *Campbell v. Purdue Pharma, L.P.*,¹⁹⁵ the court refused to certify a proposed class because the plaintiffs were unable to satisfy the numerosity requirement.¹⁹⁶ David and Belinda Campbell sought to represent a class consisting of all persons residing in the state of Missouri who were prescribed OxyContin for any condition other than moderate to severe pain caused by a terminal illness or non-chronic condition who have suffered harm as a result, including dependence, addiction or withdrawal symptoms.¹⁹⁷ The court began by observing that the plaintiffs did not have to prove that it would be impossible to join all members of the proposed class; they merely had to show that joinder would be difficult and inconvenient.¹⁹⁸ Nor would they have to establish that the precise number of class members could be determined as long as it was possible to make a reasonable estimate of their numbers.¹⁹⁹

In an attempt to satisfy this requirement, the plaintiff estimated that there were “thousands” of persons in the putative class.²⁰⁰ However, the court

¹⁹¹ *Id.*

¹⁹² FED. R. CIV. P. 23(b)(1). *See also* *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 614 (1997).

¹⁹³ *See* *Smith v. Brown & Williamson Tobacco Corp.*, 174 F.R.D. 90, 99 (W.D. Mo. 1997).

¹⁹⁴ *See Amchem Prods., Inc.*, 521 U.S. at 615.

¹⁹⁵ No. 1:02cv00163 TCM, 2004 WL 5840206 (E.D. Mo. 2004).

¹⁹⁶ *Id.* at *4.

¹⁹⁷ *Id.* at *1.

¹⁹⁸ *Id.* at *4.

¹⁹⁹ *Id.*

²⁰⁰ *Id.*

responded that this was not sufficient to constitute a "reasonable estimate."²⁰¹ The plaintiff presented evidence that OxyContin sales nationally had increased by over 1800% and that the drug was the number one prescribed Schedule II narcotic in the country, with over 7 million prescriptions for the drug written in 2002.²⁰² In view of the large number of OxyContin sales and prescriptions nationally, the court concluded that it was reasonable to assume that there would be sufficient members of the plaintiffs' proposed class to ensure that joinder of individual plaintiffs would be both impractical and inconvenient.²⁰³ However, there is a split of authority over whether national sales information is sufficient to support a finding of numerosity.²⁰⁴

The commonality requirement of Rule 23(a)(2) has been even more troublesome for plaintiffs.²⁰⁵ For example, in *Wethington v. Purdue Pharma L.P.*,²⁰⁶ an Ohio federal district court refused to certify a class, in part because the plaintiff had failed to establish commonality.²⁰⁷ The class consisted of OxyContin users from Ohio, Kentucky, Indiana and West Virginia.²⁰⁸ The plaintiffs argued that Purdue marketed and promoted OxyContin in a misleading manner and that the company knew or should have known about the harmful effects that their marketing and promotional practices would have.²⁰⁹ In addition, they maintained that the company manufactured a defective product that lacked an antagonist agent to prevent users from getting high when they crushed and ingested the drug.²¹⁰ Furthermore, the plaintiffs alleged that Purdue should be held liable for failing to properly warn consumers about the drug's side effects and for continuing to market it after the company became aware of them.²¹¹ Finally, the plaintiffs claimed that the company concealed facts about the harmful nature of OxyContin from the medical community and

²⁰¹ *Id.*

²⁰² *Id.*

²⁰³ *Id.*

²⁰⁴ Compare *Wethington v. Purdue Pharma. L.P.*, 218 F.R.D. 577 (S.D. Ohio 2003) (finding that the numerosity requirement was satisfied), with *Gevedon v. Purdue Pharma*, 212 F.R.D. 338 (E.D. Ky. 2002) (finding that the plaintiff had not established numerosity), and *Foister v. Purdue*, No. Civ.A. 01-268-DCR, 2002 WL 1008608 (E.D. Ky. 2002) (finding that the plaintiff had not established numerosity).

²⁰⁵ See *Campbell v. Purdue Pharma, L.P.*, No. 1:02cv00163 TCM, 2004 WL 5840206, at *7 (E.D. Mo. 2004); *Harris v. Purdue Pharma, L.P.*, 218 F.R.D. 590, 596 (S.D. Ohio 2003); *Wethington v. Purdue Pharma L.P.*, 218 F.R.D. 577, 589 (S.D. Ohio 2003).

²⁰⁶ 218 F.R.D. 577 (S.D. Ohio 2003).

²⁰⁷ *Id.* at 589.

²⁰⁸ *Id.* at 581.

²⁰⁹ *Id.* at 586.

²¹⁰ *Id.* at 586-87.

²¹¹ *Id.* at 587.

from the public.²¹² According to the plaintiffs, these allegations raised issues of law and fact that were common to the class.²¹³

Purdue, on the other hand, maintained that no common issues existed because all of the plaintiffs' allegations related to the defendant's conduct and ignored the individualized medical histories of the various class members.²¹⁴ Furthermore, because the drug company did not engage in direct-to-consumer advertising and directed their marketing efforts at physicians, it would be necessary for the plaintiffs to show how each one was exposed to misleading marketing and thereby misled.²¹⁵ Finally, because many of the class members crushed or otherwise misused OxyContin, resolution of their cases would depend on applicability of the product misuse defense in the various states where they resided.²¹⁶

Relying on the reasoning of *Foister v. Purdue Pharma, L.P.*,²¹⁷ the court noted that the factual circumstances of addiction are highly individualized.²¹⁸ It also concluded that the existence of the learned intermediary doctrine might affect the validity of the claims of individual class members. Consequently, the court concluded that the plaintiffs failed to meet the commonality requirement of Rule 23(a)(2).²¹⁹

A similar issue arose in *Harris v. Purdue Pharma, L.P.*²²⁰ The plaintiffs in that case alleged that Purdue and Abbott misrepresented and minimized the risks of addiction and directed their sales efforts at "opioid naïve" physician and patients.²²¹ They also claimed that OxyContin's design was defective because the drug failed to deliver sufficient amounts over the twelve-hour period for which it was designed to provide pain relief.²²² In addition, the plaintiffs argued that Purdue failed to design the drug with a narcotic antagonist.²²³ If an antagonist had been incorporated into the drug's formulation, it would have reduced the high that would otherwise result from defeating the drug's time-release feature.²²⁴ The plaintiffs asked the court to

²¹² *Id.*

²¹³ *Id.* at 586.

²¹⁴ *Id.* at 587.

²¹⁵ *Id.*

²¹⁶ *Id.*

²¹⁷ *Foister v. Purdue*, No. Civ.A. 01-268-DCR, 2002 WL 1008608, at *8 (E.D. Ky. 2002).

²¹⁸ *Wethington*, 218 F.R.D. at 588–89.

²¹⁹ *Id.* at 589.

²²⁰ 218 F.R.D. 590 (S.D. Ohio 2003).

²²¹ *Id.* at 592.

²²² *Id.*

²²³ *Id.*

²²⁴ *Id.*

order the defendants to institute a medical and prescription monitoring program for OxyContin users in order to prevent and treat addiction.²²⁵ The proposed class consisted of all citizens of the United States for whom OxyContin was prescribed and who are at risk for addiction but who have not yet suffered any personal injury.²²⁶

Addressing the commonality issue, the court declared that all of the plaintiffs' "central factual issues" were concerned with whether the defendants misrepresented the efficacy or risks of OxyContin or promoted for inappropriate uses.²²⁷ According to the court, these issues could only be resolved on an individualized basis. As far as the misrepresentation claim was concerned, the existence of the learned intermediary rule vitiated any common marketing issues because it would require the parties to determine whether each doctor was deceived by the defendants' alleged misrepresentation and as a result prescribed OxyContin to a particular patient.²²⁸ As far as the design defect claims were concerned, the court observed that any assertion of a misuse defense by the defendants would require individualized inquiries with respect to those class members who crushed or otherwise misused the drug.²²⁹ Based on this analysis, the court refused to certify the class because the plaintiffs failed to meet the commonality requirement.²³⁰

Several courts have addressed the typicality requirement.²³¹ One of these was the *Campbell* case, discussed earlier.²³² The plaintiffs in that case brought suit on behalf of a class consisting of all persons residing in the state of Missouri who had taken OxyContin for any condition other than moderate to severe pain caused by a terminal illness or non-chronic condition and who had consequently suffered harm.²³³ Although the court rejected class certification on commonality grounds, it also determined that the plaintiffs had not satisfied Rule 23(a)(3)'s typicality requirement.²³⁴

The court began by stating that "[t]he typicality requirement primarily focuses on whether the named plaintiff's claims have the same essential

²²⁵ *Id.*

²²⁶ *Id.*

²²⁷ *Id.* at 596.

²²⁸ *Id.*

²²⁹ *Id.* at 597.

²³⁰ *Id.*

²³¹ See *Campbell v. Purdue Pharma, L.P.*, No. 1:02cv00163 TCM, 2004 WL 5840206 (E.D. Mo. 2004); *Gevedon v. Purdue Pharma*, 212 F.R.D. 333 (E.D. Ky. 2002); *Foister v. Purdue Pharma*, No. Civ.A. 01-268-DCR, 2002 WL 1008608 (E.D. Ky. 2002).

²³² See *Campbell*, 2004 WL 5840206.

²³³ *Id.* at *1.

²³⁴ *Id.* at *9.

characteristics as the claims of the class at large and is designed to prevent an instance where the legal theories of the named plaintiff may potentially conflict with those of absent plaintiffs.”²³⁵ The court then declared that it must examine David Campbell’s medical history in order to determine whether his claims against Purdue were essentially the same as the claims of other class members.²³⁶ These records revealed that between 1999 and 2003, Campbell had obtained 436 prescriptions for OxyContin and numerous other synthetic narcotics.²³⁷ Consequently, the court reasoned, the propriety of OxyContin being prescribed for Campbell would necessarily require consideration of his other medications.²³⁸ The other plaintiff, Campbell’s spouse, Belinda, had a similar medical history. During the same period, she obtained 247 prescriptions, including OxyContin and other opioids.²³⁹ The court concluded that the character of the plaintiffs’ prescription drug use illustrated “the individual nature of any inquiry into the essential element of causation, even as to the ‘typical’ claims of the putative class representatives.”²⁴⁰ Accordingly, the court determined that the Campbells’ claims were not typical of the class because of the varied dosages of OxyContin that they took, as well as their use of other opioids and medications, and the availability of various affirmative defenses.²⁴¹

Rule 23’s final requirement is adequacy.²⁴² Although this requirement has not been much of an issue in OxyContin litigation, it has come up on a few occasions.²⁴³ For example, in *Gevedon v. Purdue Pharma*,²⁴⁴ the plaintiffs sought to certify a class which included “[a]ll persons in the Commonwealth of Kentucky who have obtained OxyContin and/or who obtain OxyContin in the future.”²⁴⁵ The court construed this to mean that the proposed class would consist of persons who “obtained” OxyContin (legally or otherwise) and who suffered addiction or other medical conditions.²⁴⁶ Although the court refused

²³⁵ *Id.* at *8 (quoting *Dhamer v. Bristol-Myers Squibb Co.*, 183 F.R.D. 520, 526 (N.D. Ill. 1998)).

²³⁶ *Id.*

²³⁷ *Id.*

²³⁸ *Id.*

²³⁹ *Id.* at *9.

²⁴⁰ *Id.*

²⁴¹ *Id.*

²⁴² FED. R. CIV. P. 23(a)(4).

²⁴³ See *Gevedon v. Purdue Pharma L.P.*, 212 F.R.D. 333 (E.D. Ky. 2002); *Foister v. Purdue Pharma*, 2002 WL 1008608 (E.D. Ky. 2002).

²⁴⁴ 212 F.R.D. 333 (E.D. Ky. 2002).

²⁴⁵ *Id.* at 336.

²⁴⁶ *Id.*

certification because of the lack of a definable, identifiable class, it decided to consider if the Rule 23(a) requirements were met "out of an abundance of caution."²⁴⁷

Having concluded that the plaintiff failed to establish numerosity, commonality and typicality,²⁴⁸ the court turned to the issue of adequacy. It endorsed the Sixth Circuit's two-part analysis from *Senter v. GMC*,²⁴⁹ which required that "(1) [the representatives must] have common interests with unnamed members of the class and (2) [it must appear that the representatives] will vigorously prosecute the interests of the class through qualified counsel."²⁵⁰ The court observed that the complaint averred that the plaintiffs "will fairly and adequately represent and protect the interests of the Class Members because Plaintiffs have no interest adverse to the interests of the Class."²⁵¹ The complaint also declared that "[p]laintiffs have retained counsel experienced [sic] and competent in the prosecution of class actions and complex litigation."²⁵² However, the court concluded that these assertions merely parroted the language of Rule 23(a)(4) and failed to provide any factual evidence to support them.²⁵³ Consequently, the court concluded that the plaintiffs had failed to meet the adequacy requirement and refused to certify the class.²⁵⁴

Two other OxyContin class action cases are also worthy of note. The first of these cases, *Salisbury v. Purdue Pharma, L.P.*,²⁵⁵ involved the fraudulent joinder of two Kentucky pharmacies as defendants in order to strip the federal court of its diversity jurisdiction under 28 U.S.C. § 1332.²⁵⁶ The plaintiff brought a class action in Kentucky state court against nine drug companies and two pharmacies based on their manufacture, distribution or sale of OxyContin.²⁵⁷ The suit was removed to federal district court at the out-of-state defendants' request, and the plaintiff moved to remand, arguing that the parties were not completely diverse and, therefore, the court lacked jurisdiction on diversity grounds.²⁵⁸

²⁴⁷ *Id.* at 337.

²⁴⁸ *Id.* at 337-40.

²⁴⁹ 532 F.2d 511, 524-25 (6th Cir. 1976).

²⁵⁰ *Gevedon*, 212 F.R.D. at 340.

²⁵¹ *Id.* at 341.

²⁵² *Id.*

²⁵³ *Id.*

²⁵⁴ *Id.*

²⁵⁵ 166 F. Supp. 2d 546 (E.D. Ky. 2001).

²⁵⁶ *Id.* at 548.

²⁵⁷ *Id.*

²⁵⁸ *Id.*

Citing a recent decision by the Sixth Circuit,²⁵⁹ the court declared that fraudulent joinder was applicable:

(1) when there is no colorable basis for a claim against the non-diverse defendant, (2) when a plaintiff engages in outright fraud in pleading jurisdictional allegations, and (3) when the plaintiff joins a defendant who has no joint, several, or alternative liability with a diverse defendant (and there is no nexus between the claims against the diverse and non-diverse defendant).²⁶⁰

According to the *Salisbury* court, the fraudulent joinder issue depended on whether there was a reasonable chance that the non-diverse party would be held liable to the plaintiff.²⁶¹ The court found no such prospect of liability between the pharmacies and the plaintiff because the plaintiff's complaint failed to allege that the defendant pharmacies sold OxyContin to him.²⁶² In addition, the court concluded that Kentucky's "middleman" statute²⁶³ barred the plaintiffs from recovering against the pharmacies even if they had sold OxyContin to him.²⁶⁴ Consequently, the court denied the plaintiff's request to remand the case back to state court.²⁶⁵

In the second case, *DaWalt v. Purdue Pharma, L.P.*,²⁶⁶ a federal appeals court ruled that it lacked the power to review a lower court's remand order.²⁶⁷ In 2001, the plaintiffs brought a class action against Purdue and Abbott in state court, alleging "wrongful manufacture, marketing, promotion, sale and distribution of OxyContin."²⁶⁸ The plaintiffs sought compensation for injuries stemming from OxyContin use, and asserted a claim for medical monitoring.²⁶⁹ At the same time, the plaintiffs sought to ensure that the suit would remain in state court by stipulating that the claim for each member of the class would not exceed \$75,000, the jurisdictional amount-in-controversy requirement for the diversity jurisdiction statute.²⁷⁰ Nevertheless, the

²⁵⁹ See *Jerome-Duncan, Inc. v. Auto-By-Tel, L.L.C.*, 176 F.3d 904 (6th Cir. 1999).

²⁶⁰ *Salisbury*, 166 F. Supp. 2d at 548.

²⁶¹ *Id.* at 548–49.

²⁶² *Id.* at 550.

²⁶³ KY. REV. STAT. ANN. § 411.340 (LexisNexis 2013).

²⁶⁴ *Salisbury*, 166 F. Supp. 2d at 550–51.

²⁶⁵ *Id.* at 552.

²⁶⁶ 397 F.3d 392 (6th Cir. 2005).

²⁶⁷ *Id.* at 394.

²⁶⁸ *Id.*

²⁶⁹ *Id.* at 395.

²⁷⁰ *Id.*

defendants sought to remove the case to federal court over the plaintiffs' objections.²⁷¹ In an attempt to stay within the \$75,000 limit, the plaintiffs argued that the cost of their medical monitoring claims should not be taken into account because they might be invalid under state law.²⁷²

Eventually, the Kentucky Supreme Court held that medical monitoring claims were invalid absent proof of existing physical injury.²⁷³ The federal district court subsequently remanded the case for lack of subject matter jurisdiction.²⁷⁴ Sometime later, the Sixth Circuit held that Congress's adoption of 28 U.S.C. § 1367 required district courts to aggregate the claims of class members for purposes of calculating the amount in controversy.²⁷⁵ The district court did not do this when it concluded that the plaintiffs' claims did not meet the \$75,000 requirement for diversity jurisdiction.²⁷⁶ After discussing a number of decisions interpreting the power of appellate courts to review post-removal decisions by lower courts, the court in *DaWalt* concluded that it did not have the power to review the district court's decision to remand the case back to state court for lack of diversity jurisdiction.²⁷⁷

III. *PARENS PATRIAE* LAWSUITS

Parens patriae lawsuits brought against Purdue by state officials have been far more successful than individual suits or class actions. In a *parens patriae* action, the state contends that it has standing to sue to protect its "quasi-sovereign" interests.²⁷⁸ A quasi-sovereign interest is one that is distinct from the interests of particular parties and includes such things as an "interest in the health and well-being—both physical and economic—of its residents in general."²⁷⁹ The *parens patriae* concept originated in England as an aspect of the royal prerogative which enabled the Crown to act on behalf of people who were unable to care for themselves or their property because of minority, insanity or mental incapacity.²⁸⁰ In recent years, state officials have invoked the principle of *parens patriae* to sue tobacco companies in order to recoup some

²⁷¹ *Id.*

²⁷² *Id.*

²⁷³ *Wood v. Wyeth-Ayerst Labs.*, 82 S.W.3d 849, 855 (Ky. 2002).

²⁷⁴ *DaWalt*, 397 F.3d at 396.

²⁷⁵ *Olden v. Lafarge Corp.*, 383 F.3d 495 (6th Cir. 2004).

²⁷⁶ *DaWalt*, 397 F.3d at 396.

²⁷⁷ *Id.* at 398–99.

²⁷⁸ *See Gifford, supra* note 22, at 931.

²⁷⁹ *See Alfred L. Snapp & Son, Inc. v. Puerto Rico ex rel. Barez*, 458 U.S. 592, 607 (1982).

²⁸⁰ *Id.* at 600. The term "*parens patriae*" means "parent of the country." *Id.*; *see Hawaii v. Standard Oil Co.*, 405 U.S. 251, 257 (1972).

of the social costs that these products have caused, particularly to state Medicaid programs.²⁸¹

Although these lawsuits were brought in the state's name, many of them, particularly in the case of tobacco litigation, were actually financed and managed by private law firms who were compensated on a contingent fee basis.²⁸² Almost all of these lawsuits were eventually settled, in part because defendants could not afford the high costs of extended litigation.²⁸³ The largest settlement involved the tobacco industry, which agreed to pay the states \$206 billion over a 25-year period²⁸⁴ and also agreed to various conditions respecting the promotion and sale of its products.²⁸⁵ The success of these suits against tobacco companies led some states to bring similar actions against the manufacturers of firearms²⁸⁶ and lead paint.²⁸⁷

Litigants in these government lawsuits have relied on a variety of liability theories, including unjust enrichment and restitution, negligent entrustment, engaging in an abnormally dangerous activity, negligent marketing and public nuisance.²⁸⁸ However, for the most part, the viability of theories has not been tested in the courts because most of these cases have been settled prior to trial.²⁸⁹ Furthermore, it should be mentioned that defendants

²⁸¹ See generally Richard C. Ausness, *Public Tort Litigation: Public Benefit or Public Nuisance?*, 77 TEMP. L. REV. 825, 828–37 (2004).

²⁸² See Michael DeBow, *The State Tobacco Litigation and the Separation of Powers in State Governments: Repairing the Damage*, 31 SETON HALL L. REV. 563, 568 (2001).

²⁸³ See Howard M. Erichson, *Coattail Class Actions: Reflections on Microsoft, Tobacco, and the Mixing of Public and Private Lawyering in Mass Litigation*, 34 U.C. DAVIS L. REV. 1, 10 (2000).

²⁸⁴ See Bryce A. Jensen, Note, *From Tobacco to Health Care and Beyond—A Critique of Lawsuits Targeting Unpopular Industries*, 86 CORNELL L. REV. 1334, 1335 (2001).

²⁸⁵ See Frederickson, *supra* note 2, at 135.

²⁸⁶ See *People ex rel. Spitzer v. Sturm, Ruger & Co.*, 761 N.Y.S.2d 192 (N.Y. App. Div. 2003). However, most of the lawsuits against firearms manufacturers were brought by municipalities rather than by states. See Doug Morgan, Comment, *What in the Wide, Wide World of Torts Is Going On? First Tobacco, Now Guns: An Examination of Hamilton v. Accu-Tek and the Cities' Lawsuits Against the Gun Industry*, 69 MISS. L.J. 521 (1999); Frank J. Vandall, O.K. Corral II: Policy Issues in Municipal Suits Against Gun Manufacturers, 44 VILL. L. REV. 547 (1999).

²⁸⁷ See *State v. Lead Indus. Ass'n*, 951 A.2d 428 (R.I. 2008). See also Richard L. Cupp, Jr., *State Medical Reimbursement Lawsuits After Tobacco: Is the Domino Effect for Lead Paint Manufacturers and Others Fair Game?*, 27 PEPP. L. REV. 685 (2000); Amber E. Dean, Comment, *Lead Paint Public Entity Lawsuits: Has the Broad Stroke of Tobacco and Firearms Litigation Painted a Troubling Picture for Lead Paint Manufacturers?*, 28 PEPP. L. REV. 915 (2001).

²⁸⁸ Ausness, *supra* note 281, at 856.

²⁸⁹ *Id.* at 856–63.

have sometimes been able to respond with defenses such as lack of standing, lack of proximate cause, no duty, and failure to show a physical injury.²⁹⁰

Two of the most promising liability theories are negligent marketing and public nuisance. Negligent marketing has already been discussed above. In *parens patriae* cases, negligent marketing claims usually focus on the targeting of vulnerable segments of the population and failure to supervise distribution of the product at the retail level.²⁹¹ Public nuisance is another popular liability theory.²⁹² A public nuisance is an unreasonable interference with rights that are held in common by the general public.²⁹³ The Restatement of Torts identifies three factors that are relevant to whether interference is unreasonable.²⁹⁴ One consideration is whether the defendant's conduct significantly interferes with the public health, safety, peace, comfort or convenience.²⁹⁵ A second factor is whether the defendant's conduct violates a statute, ordinance or administrative regulation.²⁹⁶ A final concern is whether the conduct is of a continuing nature or will produce a permanent long-lasting effect on the public right in question.²⁹⁷

Although a number of state attorneys general have brought suit against Purdue, two lawsuits are particularly significant. The first involved the state of West Virginia. In 2001, West Virginia's Attorney General filed suit against Purdue based on its production, promotion, marketing and distribution of OxyContin.²⁹⁸ The complaint accused the drug company of violating the state's Consumer Credit Protection Act, maintaining a public nuisance, engaging in negligent conduct and violating West Virginia's antitrust statutes.²⁹⁹ The complaint sought restitution for unjust enrichment, indemnity and an order mandating medical monitoring for West Virginia OxyContin users.³⁰⁰ The complaint alleged that West Virginia state agencies incurred more than \$30 million in OxyContin related costs between 1996 and 2003.³⁰¹ It also charged that Purdue's aggressive marketing of OxyContin caused excessive,

²⁹⁰ *Id.*

²⁹¹ See Gifford, *supra* note 22, at 942–43.

²⁹² See Donald G. Gifford, *Public Nuisance as a Mass Products Liability Tort*, 71 U. CIN. L. REV. 741, 743 (2003).

²⁹³ RESTATEMENT (SECOND) OF TORTS § 821B (1979).

²⁹⁴ *Id.* § 821B(2).

²⁹⁵ *Id.* § 821B(2)(a).

²⁹⁶ *Id.* § 821B(2)(b).

²⁹⁷ *Id.* § 821B(2)(c).

²⁹⁸ See Prater, *supra* note 6, at 1424.

²⁹⁹ *Id.* at 1425.

³⁰⁰ *Id.*

³⁰¹ *Id.*

inappropriate and unnecessary prescriptions of OxyContin to be written during that period.³⁰² As a result, the complaint declared, “citizens and consumers of West Virginia, who have legitimately and legally paid for OxyContin, have incurred actual damages and excessive costs.”³⁰³ In its complaint, West Virginia sought “restitution and reimbursement sufficient to cover all costs expended for health care services and programs associated with the diagnosis and treatment of adverse health consequences of OxyContin use, including, but not limited to, addiction due to defendants’ wrongful conduct.”³⁰⁴ In addition, the state requested compensation for all prescription costs for OxyContin that it had incurred as a result of the defendants’ wrongful conduct.³⁰⁵

Eventually, in November 2004 the case was settled for the comparatively small sum of \$10 million.³⁰⁶ The fact that West Virginia was willing to settle for such a small amount suggests that the Attorney General’s lawyers realized that there was no assurance that the state would ultimately prevail if the case went to trial. A particular concern was that a court would conclude that misuse of OxyContin by drug abusers was a superseding cause sufficient to break the chain of causation between Purdue’s marketing activities and the costs the state incurred to treat the effects of such abuse.³⁰⁷ Nevertheless, the West Virginia settlement apparently prompted 26 other states and the District of Columbia to bring a class action against Purdue, accusing the company of promoting off-label uses of OxyContin and failing to disclose the diversion and addiction risks associated with the drug.³⁰⁸ Purdue settled this case in 2007 and agreed to pay the states \$19.5 million.³⁰⁹ In the settlement, Purdue also agreed to a number of restrictions on future marketing practices and managerial procedures.³¹⁰

In October 2007, the Commonwealth of Kentucky, along with Pike County, brought suit against Purdue and Abbott.³¹¹ The complaint alleged that

³⁰² *Id.*

³⁰³ Complaint at 18, West Virginia *ex rel.* McGraw v. Purdue Pharma L.P., No. 01-C-137S (W. Va. Cir. Ct. June 11, 2001).

³⁰⁴ *Id.* at 21.

³⁰⁵ *Id.*

³⁰⁶ See Christopher R. Page, Comment, *These Statements Have Not Been Approved by the FDA: Improving the Postapproval Regulation of Prescription Drugs*, 88 OR. L. REV. 1189, 1205 (2009).

³⁰⁷ See Prater, *supra* note 6, at 1410–11.

³⁰⁸ *Id.* at 1434.

³⁰⁹ See Ashley L. Taylor, Jr. et al., *Recent Developments in Government Operations and Liability: State Attorneys General: The Robust Use of Previously Ignored State Powers*, 40 URB. LAW. 507, 513 (2008).

³¹⁰ See Frederickson, *supra* note 2, at 135.

³¹¹ *In re OxyContin Antitrust Litig.*, 821 F. Supp. 2d 591, 593 (S.D.N.Y. 2011).

the defendants' sales representatives marketed and promoted OxyContin to medical care providers between December 1995 and June 2001 claiming that it was "less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications" despite the fact that company officials knew that these assertions were false and misleading.³¹² The complaint further declared that these misrepresentations and omissions prevented physicians and patients from ascertaining the appropriate uses and inherent risks of OxyContin and thereby induced physicians to prescribe the drug more often than they otherwise would have.³¹³ As a result, a large number of Kentucky residents became addicted to OxyContin and consequently suffered serious health problems or engaged in criminal acts in order to obtain the drug.³¹⁴

Furthermore, the Commonwealth contended that the defendants' wrongful marketing and promotion practices caused the state to pay for unnecessary prescriptions and provide medical services that would not have otherwise been required were it not for the defendants' deceptive practices.³¹⁵ In addition, Pike County alleged that it spent millions of dollars to "investigate, apprehend, prosecute and incarcerate" individuals who have resorted to criminal acts to support the cost of their addiction.³¹⁶ Based on these allegations, the complaint sought damages, indemnity, restitution, punitive damages and equitable relief on the following grounds: (1) violation of the state's Medicaid Fraud Statute;³¹⁷ (2) violation of the Kentucky False Advertising Statute;³¹⁸ (3) public nuisance; (4) unjust enrichment; (4) negligence; (5) violation of state antitrust law; (5) strict liability; (6) common law fraud; (7) as well as conspiracy and concert of action.³¹⁹ The Commonwealth relied on KRS § 15.060, which authorized the Attorney General to recover funds that had been fraudulently paid out of the state treasury.³²⁰

After the plaintiffs filed their case in state court, Purdue succeeded in removing the case to the federal district court in the Eastern District of Kentucky, claiming federal subject matter jurisdiction under 28 U.S.C. § 1331

³¹² *Id.* at 594.

³¹³ *Id.*

³¹⁴ *Id.*

³¹⁵ *Id.*

³¹⁶ *Id.*

³¹⁷ KY. REV. STAT. ANN. §§ 205.8463, 446.070 (LexisNexis 2013).

³¹⁸ *Id.* §§ 517.030, 446.070.

³¹⁹ *In re OxyContin*, 821 F. Supp. 2d at 594.

³²⁰ *Id.*

and § 1332(d)(2)(A).³²¹ Later, in April 2008, the Multi-District Litigation panel transferred the action to a New York federal district court for consolidation with other OxyContin cases involving antitrust claims against Purdue.³²² The reason for the removal to another court was that the plaintiffs had included an antitrust claim against the defendants in their complaint.³²³ Two years later, Kentucky moved, pursuant to 28 U.S.C. § 1447(c), to remand the case back to the Kentucky state court where the action had originally been filed, claiming that removal of the case from state court had been improper because the federal court lacked subject matter jurisdiction.³²⁴ Purdue opposed the motion on the grounds that the district court had federal question jurisdiction and the case was a putative class action that could be removed to federal court under the Class Action Fairness Act of 2005 (CAFA).³²⁵ Thus began the long, and ultimately successful, battle to have this case tried in state court.

The court began with the federal jurisdiction issue and observed that 28 U.S.C. § 1331 permits a defendant to remove a civil suit from state court to a federal court if the action is deemed to be one “arising under” federal law.³²⁶ The court also declared that “the plaintiff’s right to relief [on a state law claim] necessarily depends on resolution of a substantial question of federal law.”³²⁷ In this case, Purdue argued that some of the Commonwealth’s claims required the resolution of a substantial question of federal law.³²⁸ To resolve this issue, the court followed the criteria set forth by the United States Supreme Court in *Grable & Sons Metal Products, Inc. v. Darue Eng’g & Mfg.*³²⁹ In that case, the Court identified three conditions that were essential to federal jurisdiction: “does a state-law claim necessarily raise a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities.”³³⁰

As an initial matter, in other cases where state officials have sued drug companies for reimbursement of Medicaid-related expenses, the court observed that a great majority of federal courts ruled that they did not have federal

³²¹ *Id.* at 594–95.

³²² *Id.* at 595.

³²³ *Id.*

³²⁴ *Id.*

³²⁵ 28 U.S.C. § 1332(d)(2)(A) (2012).

³²⁶ *In re OxyContin*, 821 F. Supp. 2d at 595.

³²⁷ *Id.* (citing *Empire Healthchoice Assurance, Inc. v. McVeigh*, 547 U.S. 677, 689–90 (2006)).

³²⁸ *Id.* at 595–96.

³²⁹ 545 U.S. 308, 314 (2005).

³³⁰ *Id.*

question jurisdiction and remanded the cases to state court.³³¹ Turning to the first of the *Grable* requirements, the court considered whether the plaintiffs' state-law claims necessarily raised a federal issue.³³² Purdue argued that the complaint alleged two theories of fraud, indirect and direct, each of which necessarily involved the question of whether Kentucky was "legally obligated" to pay for unnecessary OxyContin prescriptions and related health care costs under the federal Medicaid requirements.³³³ According to Purdue, the Commonwealth could not recover under its indirect theory of fraud, namely that health care providers and patients reasonably relied on Purdue's alleged misrepresentations, unless it was required under federal law to pay these expenses.³³⁴ The fraud was indirect because Purdue allegedly lied to doctors and patients rather than directly to the Commonwealth.³³⁵

Purdue also maintained that under the direct theory of fraud, the company failed to fully disclose material information to Commonwealth officials about the addictive nature of OxyContin, an issue of federal law was involved because Medicaid law severely restricted the state's ability to limit or restrict coverage for any outpatient drugs subject to a Medicaid rebate agreement.³³⁶ According to Purdue, the direct fraud claim assumed that Kentucky would not have paid for these OxyContin prescriptions had the misrepresentations not occurred, but under federal law, the state would have had to pay for the prescriptions even if Purdue had fully disclosed the risks of addiction.³³⁷

In response, the court disputed Purdue's contention that Kentucky could not prevail under its indirect fraud claim without proving that federal law required it to pay for the Medicaid-related expenses that it was seeking to recover from the drug company.³³⁸ The court declared that Purdue had failed to produce "any relevant legal authority for the proposition that the Commonwealth . . . was legally obligated, under federal law or otherwise, to pay for the Medicaid-related expenses it seeks to recover in order to prevail on its indirect theory of fraud."³³⁹ Consequently, the court held that Purdue had failed to show that the Commonwealth's assertion of its indirect fraud theory

³³¹ *In re OxyContin*, 821 F. Supp. 2d at 596.

³³² *Id.* at 597.

³³³ *Id.* at 597-98.

³³⁴ *Id.* at 598.

³³⁵ *Id.* at 597-98.

³³⁶ *Id.*

³³⁷ *Id.*

³³⁸ *Id.*

³³⁹ *Id.*

necessarily raised a federal issue.³⁴⁰ The court also ruled that it need not decide whether the direct theory of fraud necessarily raised a federal issue.³⁴¹ It reasoned that that since the Commonwealth could recover under the indirect theory of fraud, which did not involve a federal issue, it did not matter whether its alternative theory of direct fraud did involve such a question.³⁴²

Turning to the second *Grable* requirement, the court concluded that even if the Commonwealth's indirect theory of fraud necessarily raised a federal issue, Purdue failed to show that this issue was disputed or substantial.³⁴³ It noted that the Commonwealth did not dispute that it had a legal obligation to reimburse Medicaid claims for OxyContin prescriptions.³⁴⁴ Kentucky's claim, which was that Purdue wrongly triggered its obligation to pay for OxyContin prescriptions, did not require an interpretation of the Medicaid statute or an assessment of its obligation to pay under that statute.³⁴⁵ Instead, it merely required a court to determine whether Kentucky's claim had any merit under state law.³⁴⁶ Therefore, the court concluded that the state's lawsuit against Purdue did not raise a federal issue that was either disputed or substantial.³⁴⁷

Finally, the court considered whether a federal forum could adjudicate Kentucky's claim "without disturbing any congressionally approved balance of federal and state judicial responsibilities" and concluded that it could not.³⁴⁸ The court acknowledged that Congress has specifically required the states to seek reimbursement of Medicaid funds from legally liable third parties,³⁴⁹ but pointed out it did not create a federal cause of action to recover these funds.³⁵⁰ The court declared that this omission suggested that Congress intended for these reimbursement suits to be brought in state courts.³⁵¹ The court also concluded that considerations of comity weighed against removing cases from

³⁴⁰ *Id.*

³⁴¹ *Id.* at 599.

³⁴² *Id.* (citing *Broder v. Cablevision Sys. Corp.*, 418 F.3d 187, 194 (2d Cir. 2005)).

³⁴³ *Id.*

³⁴⁴ *Id.*

³⁴⁵ *Id.* at 599–600.

³⁴⁶ *Id.* at 600.

³⁴⁷ *Id.*

³⁴⁸ *Id.*

³⁴⁹ *Id.* (citing 42 U.S.C. § 1396a(a)(25)(A) (2012)).

³⁵⁰ *Id.*

³⁵¹ *Id.*

state court unless some clear rule demanded it.³⁵² Thus, the court determined that it lacked federal question jurisdiction according to the *Grable* decision.³⁵³

Purdue also argued that the Attorney General's lawsuit was properly removed to federal court under CAFA because it was a class action.³⁵⁴ The court noted that in order to be removable under CAFA, the matter in controversy must exceed \$5 million, there must be at least 100 plaintiffs in the proposed class and the parties must be minimally diverse.³⁵⁵ In addition, to be removed, the action must qualify as either a class action or a mass action.³⁵⁶ The court concluded that the lawsuit was not a class action because there were only two plaintiffs involved.³⁵⁷ In doing so, the court rejected Purdue's claim that Kentucky consumers were the real parties in interest.³⁵⁸ Instead, it declared that the suit was a *parens patriae* action which sought to vindicate the state's quasi-sovereign interests.³⁵⁹ Accordingly, it rejected Purdue's CAFA-based analysis and ordered the case remanded to state court.³⁶⁰

Undeterred by this defeat at the trial court level, Purdue sought to appeal the lower court's ruling to the Second Circuit Court of Appeals.³⁶¹ The federal question issue was apparently dropped and the Purdue Court focused on whether a *parens patriae* action, such as the one brought against the company by the Kentucky Attorney General, was a class action and, therefore, removable to federal court under CAFA.³⁶² The court first observed that CAFA was limited to "class actions" and "mass actions."³⁶³ Since Purdue did not contend that the Kentucky lawsuit was a "mass action,"³⁶⁴ the issue of CAFA's applicability depended upon whether it could be characterized as a "class action" under the statute.³⁶⁵ According to the court, states generally filed suits in federal court that could be described as either proprietary suits in which the state sued in much the same capacity as a private party, "sovereignty suits" to

³⁵² *Id.* (citing *Franchise Tax Bd. of Cal. v. Constr. Laborers Vacation Trust*, 463 U.S. 1, 21 n.22 (1983)).

³⁵³ *Id.*

³⁵⁴ *Id.*

³⁵⁵ *Id.* (citing 28 U.S.C. §§ 1332(d)(2), (d)(5)(B), (d)(2)(A) (2012)).

³⁵⁶ *Id.* at 601.

³⁵⁷ *Id.*

³⁵⁸ *Id.* at 601–02.

³⁵⁹ *Id.* at 601.

³⁶⁰ *Id.* at 603.

³⁶¹ *See Purdue Pharma L.P. v. Kentucky*, 704 F.3d 208, 211 (2d Cir. 2013).

³⁶² *Id.* at 212.

³⁶³ *Id.* at 213.

³⁶⁴ *Id.* at 214 n.5.

³⁶⁵ *Id.* at 214.

determine such issues as boundary disputes or water rights, or *parens patriae* suits to protect “quasi-sovereign” interests.³⁶⁶

The court noted that the Attorney General sought to enforce the state’s rights under two separate statutes. The first of these, KRS § 446.070, created a general private right of action on behalf of any person who was injured as the result of a violation of statute.³⁶⁷ The second statute, KRS § 15.060, authorized the Attorney General to institute legal action to recover “any fraudulent, erroneous or illegal fee bill, account, credit, charge or claim” that had been erroneously or improperly paid to someone out of the state treasury.³⁶⁸ The court concluded, neither of these statutes authorized a class action, nor did they “bear any resemblance to Rule 23.”³⁶⁹ Furthermore, the court pointed out that the complaint made no mention of Kentucky Rule of Civil Procedure 23 (KRCP 23), the state law analog to the federal class action provision.³⁷⁰

Purdue argued that even though the complaint did not mention KRCP 23, the Attorney General was actually relying on its provisions to assert representative claims for restitution on behalf of individual OxyContin users.³⁷¹ However, the court rejected this reasoning. It declared that under CAFA, a class action was defined as a civil action “filed under” a state-law equivalent to Rule 23.³⁷² As the court exclaimed, “we are hard pressed to understand how a suit may be ‘filed under’ a statute or rule that does not even appear on the face of the complaint.”³⁷³ Moreover, the court pointed out, a state-law equivalent to Rule 23 must at least provide a procedure by which a member of a class whose claim is typical of other class members can bring an action on behalf of himself and all others in the class.³⁷⁴ However, *parens patriae* actions, such as the one in question, had few, if any, class-like characteristics.³⁷⁵ Accordingly, the court concluded that “[i]n form as well as in function,” *parens patriae* suits were not equivalent to Rule 23 as required by CAFA.³⁷⁶ Since the Attorney General’s suit was not a class action as defined by CAFA, the court determined that Purdue’s request to appeal should be denied.³⁷⁷

³⁶⁶ *Id.* at 215 (citing *Connecticut v. Cahill*, 217 F.3d 93, 97 (2d Cir. 2000)).

³⁶⁷ *Id.*

³⁶⁸ *Id.* at 215–16.

³⁶⁹ *Id.* at 216.

³⁷⁰ *Id.*

³⁷¹ *Id.* at 216 n.7.

³⁷² *Id.*

³⁷³ *Id.* at 216.

³⁷⁴ *Id.* at 217.

³⁷⁵ *Id.*

³⁷⁶ *Id.*

³⁷⁷ *Id.* at 220–21.

As of June, 2013, Pike County had settled its claims against Purdue for approximately \$4 million.³⁷⁸ The money was to be used to expand a planned drug rehabilitation facility in the Pike County Justice Hall.³⁷⁹ Meanwhile, the Attorney General's suit against Purdue was progressing through the state courts.³⁸⁰

IV. CRIMINAL PROSECUTIONS

Another potential solution to OxyContin abuse is to step up criminal prosecutions of those who violate drug laws. In its early stages, the federal government's "War on Drugs" focused on sale and use of illegal drugs such as cocaine, heroin, and marijuana. This resulted in the prosecution of thousands of drug users in addition to producers and distributors. As a result, the prisons quickly filled to overflowing with drug offenders and small-time drug dealers.³⁸¹ Unfortunately, this effort failed to significantly reduce illicit drug use. This suggests that increasing criminal penalties for prescription drug abuse or ramping up enforcement of drug laws will probably do little to curb the abuse of drugs like OxyContin. However, enforcing criminal sanctions against those who manufacture or supply products like OxyContin to drug abusers may prove to be more productive than prosecuting drug abusers themselves. In the case of OxyContin, the federal government has secured the conviction of a number of drug companies, physicians and pharmacists for violating the Controlled Substances Act and other statutes.

³⁷⁸ See Al Cross, *Pike County Settles its Part of Oxycontin Lawsuit Against Purdue Pharma for \$4 Million; State Remains a Plaintiff*, KENTUCKY HEALTH NEWS (June 8, 2013), <http://kyhealthnews.blogspot.com/2013/06/pike-county-settles-its-part-of.html>.

³⁷⁹ *Id.*

³⁸⁰ *Id.*

³⁸¹ This phenomenon began around 1980. For example, between 1985 and 1996, the prison inmate population increased 237% and the incarceration rate increased from 313 per 100,000 of the general population to 615 per 100,000 during that period. Linda S. Beres & Thomas D. Griffith, *Do Three Strikes Law Make Sense? Habitual Offender Statutes and Criminal Incarceration*, 87 GEO. L.J. 103, 104 (1998). Much of this increase was due to the War on Drugs. For example, drug offenders accounted for 80% of the increase of inmates in federal prisons between 1985 and 1995. *Id.* at 107. The number of inmates incarcerated in federal prisons for drug offenses rose from 4,900 to 51,737 between 1980 and 1995. *Id.* There was an even greater increase in the number of drug offenders in state prisons during this period. *Id.* Between 1980 and 1995, the number of inmates incarcerated for drug offenses in state prisons rose from 19,000 to 224,900. *Id.* This dramatic increase in the prison population was also due to the adoption in many states of laws imposing longer sentences on habitual offenders. See Robert G. Lawson, *Difficult Times in Kentucky Corrections—Aftershocks of a "Tough on Crime" Philosophy*, 93 KY. L.J. 305, 336 (2004).

A. *Criminal Prosecution of Pharmaceutical Companies*

In the fall of 2001, the United States Attorney's Office for the Western District of Virginia began a criminal investigation of Purdue in connection with its marketing of OxyContin in Virginia.³⁸² The investigation showed that OxyContin prescriptions increased from 300,000 to six million per year in the state between 1996 and 2001.³⁸³ In addition, oxycodone-related deaths rose 400% in Virginia during the same period.³⁸⁴ As the result of this investigation, Purdue was charged with misbranding of a drug with intent to defraud and mislead.³⁸⁵ The basis of this charge was that Purdue had claimed that OxyContin was less addictive than other forms of oxycodone.³⁸⁶ In 2007, Purdue agreed to plead guilty to the misbranding charge, a felony, and three of its executives pled guilty to a lesser charge of "misbranding a drug."³⁸⁷ In its plea agreement, Purdue agreed to pay more than \$600 million in fines and other monetary penalties.³⁸⁸ In addition, Purdue's President and COO, Executive Vice President and Chief Legal Officer and Executive Vice President of Worldwide Medical Affairs were each required to pay a \$5,000 criminal fine as well as \$19 million, \$8 million and \$7.5 million respectively to the Virginia Medicaid Fraud Control Unit's Income Fund.³⁸⁹ Furthermore, after the plea agreement was accepted, the Department of Health and Human Services issued an order excluding the Purdue executives from participating in any federal health care program, including Medicare and Medicaid for a period of 20 years.³⁹⁰ This was later reduced to 12 years.³⁹¹

B. *Criminal Prosecution of Prescribing Physicians*

In 2001, the federal Drug Enforcement Administration (DEA) initiated a campaign known as the "OxyContin Action Plan" to investigate and

³⁸² Friedman v. Sebelius, 755 F. Supp. 2d 98, 100–101 (D.D.C. 2010).

³⁸³ Frederickson, *supra* note 2, at 136.

³⁸⁴ *Id.*

³⁸⁵ *Id.*

³⁸⁶ See Andrew C. Baird, Comment, *The New Park Doctrine: Missing the Mark*, 91 N.C. L. REV. 949, 983 (2013).

³⁸⁷ United States v. Purdue Frederick Co., Inc., 495 F. Supp. 2d 569, 570 (W.D. Va. 2007).

³⁸⁸ Frederickson, *supra* note 2, at 138.

³⁸⁹ *Id.* at 138. Purdue actually made these payments pursuant to an indemnification agreement between the company and its senior corporate officers. Friedman v. Sebelius, 755 F. Supp. 2d 98, 102 n.7 (D.D.C. 2010).

³⁹⁰ Friedman, 755 F. Supp. 2d at 102–03.

³⁹¹ *Id.* at 117.

prosecute doctors for improper prescribing of OxyContin.³⁹² The principal basis for these prosecutions was violation of the Controlled Substances Act (CSA). The CSA allows only those who are registered “practitioners” with the DEA to distribute or dispense a controlled substance, such as OxyContin.³⁹³ Moreover, even registered practitioners are subject to criminal liability unless the prescriptions they write are issued for a “legitimate medical purpose” and the prescribers are acting “in the usual course of their professional practice.”³⁹⁴ Thus, a physician may be held criminally liable if he or she ceases to distribute or dispense controlled substances as a medical professional and instead acts as a drug “pusher.”³⁹⁵

Not surprisingly, many of the reported cases have hinged on whether the defendant physician prescribed OxyContin for a legitimate medical purpose and in the course his or her professional practice.³⁹⁶ In addition to unlawful distribution charges, federal prosecutors have also charged some physicians with unlawful distribution of controlled substances resulting in death,³⁹⁷ conspiracy to unlawfully distribute controlled substances,³⁹⁸ money laundering,³⁹⁹ and health care fraud.⁴⁰⁰

As might be expected, defendants have raised a number of defenses, including ineffective counsel,⁴⁰¹ self-incrimination,⁴⁰² unlawful search and

³⁹² Hoffmann, *supra* note 10, at 280–81.

³⁹³ 21 U.S.C. § 823 (2012). OxyContin is a Schedule II controlled substance under the CSA. 21 C.F.R. § 1308.12(b)(1)(xiii) (2013).

³⁹⁴ 21 C.F.R. § 1306.04.

³⁹⁵ See *United States v. Moore*, 423 U.S. 122, 138 (1975).

³⁹⁶ See, e.g., *United States v. Ignasiak*, 667 F.3d 1217, 1228–29 (11th Cir. 2012); *United States v. Rosenberg*, 585 F.3d 355, 356 (7th Cir. 2009); *United States v. McIver*, 470 F.3d 550, 556 (4th Cir. 2006); *United States v. Hurwitz*, 459 F.3d 463, 475 (4th Cir. 2006); *United States v. Feingold*, 454 F.3d 1001, 1008 (9th Cir. 2006); *United States v. Williams*, 445 F.3d 1302, 1308 (11th Cir. 2006); *United States v. Alerre*, 430 F.3d 681, 690 (4th Cir. 2005); *United States v. Sawaf*, 129 Fed. App’x 136, 142 (6th Cir. 2005); *United States v. Valdivieso Rodriguez*, 532 F. Supp. 2d 316, 321–22 (D.P.R. 2007).

³⁹⁷ See, e.g., *Ignasiak*, 667 F.3d at 1219; *McIver*, 470 F.3d at 552; *Hurwitz*, 459 F.3d at 467; *Williams*, 445 F.3d at 1304.

³⁹⁸ See, e.g., *McIver*, 470 F.3d at 552; *Hurwitz*, 459 F.3d at 467; *Alerre*, 430 F.3d at 684; *Valdivieso Rodriguez*, 532 F. Supp. 2d at 319.

³⁹⁹ See, e.g., *Alerre*, 430 F.3d at 684; *Valdivieso Rodriguez*, 532 F. Supp. 2d at 319.

⁴⁰⁰ See, e.g., *Ignasiak*, 667 F.3d at 1219; *United States v. Chube*, 538 F.3d 693, 695 (7th Cir. 2008); *Williams*, 445 F.3d at 1304.

⁴⁰¹ See, e.g., *Alerre*, 430 F.3d at 688; *United States v. Sawaf*, No. 6:01-47-KKC, 6:09-7104-KKC, 2013 WL 1311395, at *1 (E.D. Ky. Mar. 27, 2013).

⁴⁰² See, e.g., *Valdivieso Rodriguez*, 532 F. Supp. 2d at 322–23.

seizure,⁴⁰³ violation of the Confrontation Clause,⁴⁰⁴ and improper sentencing.⁴⁰⁵ However, most cases involved one of two issues: (1) whether testimony or jury instructions about “professional practice” confuses the standard of proof in a criminal case with the civil standard of proof in a civil malpractice case; and (2) whether “good faith” is a defense to criminal liability for unlawful distribution. Since prescribing physicians are subject to criminal liability under the CSA only if they knowingly and intentionally act “outside the course of professional practice” and without a “legitimate medical purpose,”⁴⁰⁶ it is often necessary for a court to determine what constitutes professional practice in order to compare it with the defendant’s conduct. This usually requires expert testimony and the parties often disagree about the propriety of using large quantities of opioids to treat chronic pain.⁴⁰⁷

A recurring issue is whether evidence of the defendant’s departure from the generally recognized practices and procedures of the medical profession can be introduced to show that the defendant’s activities fell outside of the usual course of professional practice as required to prove a violation of the CSA.⁴⁰⁸ For example, in *United States v. Alerre*,⁴⁰⁹ the prosecution’s expert witness testified that the defendants’ prescription practices, which he described in detail, failed to meet the ordinary standard of care and constituted “illegitimate medicine.”⁴¹⁰ After their conviction, the defendants appealed, arguing, *inter alia*, that this testimony conflated the criminal standard with the civil standard of proof and resulted in their being tried for and convicted of civil malpractice instead of the criminal distribution of drugs.⁴¹¹ However, the court declared that evidence that a physician departed from the civil standard should not automatically be excluded.⁴¹² Instead, it concluded in this case that that “evidence that a physician consistently failed to follow generally

⁴⁰³ See, e.g., *Hurwitz*, 459 F.3d at 469–70.

⁴⁰⁴ See, e.g., *Ignasiak*, 667 F.3d at 1229–35.

⁴⁰⁵ See, e.g., *United States v. Feingold*, 454 F.3d 1001, 1013–14 (9th Cir. 2006); *Williams*, 445 F.3d at 1310–11; *Alerre*, 430 F.3d at 696; *United States v. Sawaf*, 129 Fed. App’x 136, 143–46 (6th Cir. 2005).

⁴⁰⁶ *United States v. Chube*, 538 F.3d 693, 697 (7th Cir. 2008).

⁴⁰⁷ See generally *Hoffmann*, *supra* note 10, at 284–89.

⁴⁰⁸ See *United States v. Rosenberg*, 585 F.3d 355, 357–58 (7th Cir. 2009); *United States v. McIver*, 470 F.3d 550, 556–61 (4th Cir. 2006); *Feingold*, 454 F.3d at 1009–13; *United States v. Williams*, 445 F.3d 1302, 1307–08 (11th Cir. 2006); *Alerre*, 430 F.3d at 690–92.

⁴⁰⁹ 430 F.3d at 681.

⁴¹⁰ *Id.* at 686.

⁴¹¹ *Id.* at 691.

⁴¹² *Id.*

recognized procedures tends to show that in prescribing drugs he was not acting as a healer but as a seller of wares."⁴¹³

A related issue is whether a physician may avoid liability for violating the CSA by claiming that he or she acted in "good faith."⁴¹⁴ *United States v. Hurwitz*⁴¹⁵ provides a good analysis of this issue. Dr. Hurwitz was convicted of multiple counts of drug trafficking for prescribing very high doses of OxyContin and other opioids.⁴¹⁶ In his appeal, the defendant argued that the trial court erred when it refused to instruct the jury on good faith as a defense to the drug trafficking charges.⁴¹⁷ The appeals court agreed, declaring that "a doctor's good faith generally is relevant to a jury's determination of whether a doctor acted outside the bounds of medical practice or with a legitimate medical purpose when prescribing narcotics."⁴¹⁸ Therefore, it held that the defendant was entitled to raise the question of good faith.⁴¹⁹ At the same time, the court declared that the standard for evaluating a doctor's good faith was an objective one.⁴²⁰ As the court pointed out, to recognize a subjective standard of good faith would allow a physician to substitute his or her views on what constituted good medical practice for standards that were generally recognized and accepted would seriously undermine federal drug enforcement laws.⁴²¹ Accordingly, the court ruled that the trial court was not required to accept the defendant's proposed good faith jury instruction because it set forth a subjective rather than an objective standard.⁴²² Nevertheless, the court held that jury instructions the trial court did adopt were prejudicial to the defendant and reversed his conviction.⁴²³

Finally, *United States v. Valdivieso Rodriguez*⁴²⁴ presents an interesting professional practice issue. In this case, the government charged seven physicians in Puerto Rico with dispensing controlled substances through the

⁴¹³ *Id.*

⁴¹⁴ See *United States v. Hurwitz*, 459 F.3d 463, 476–83 (4th Cir. 2006); *United States v. Feingold*, 454 F.3d 1001, 1008–09 (9th Cir. 2006).

⁴¹⁵ 459 F.3d at 463.

⁴¹⁶ *Id.* at 466.

⁴¹⁷ *Id.* at 475–76.

⁴¹⁸ *Id.* at 476.

⁴¹⁹ *Id.* at 480.

⁴²⁰ *Id.* at 478. But see Deborah Hellman, *Prosecuting Doctors for Trusting Patients*, 16 GEO. MASON L. REV. 701, 709 (2009) (criticizing the court's adoption of an objective good faith standard).

⁴²¹ *Hurwitz*, 459 F.3d at 479.

⁴²² *Id.* at 480.

⁴²³ *Id.* at 482.

⁴²⁴ 532 F. Supp. 2d 316 (D.P.R. 2007).

Internet to individuals in the absence of a doctor-patient relationship.⁴²⁵ The defendants moved to dismiss, claiming that Puerto Rico's Telemedicine Law allowed them to provide prescriptions to nonresidents of the Commonwealth and, therefore, their conduct did not fall outside the scope of professional practice.⁴²⁶ The court declared that the government should be allowed to prove that the defendants' prescribing practices, taken as a whole fell outside the bounds of professional practice.⁴²⁷ Apparently, the court felt that this issue was not foreclosed by the fact that Internet sales of prescription drugs were authorized by the Puerto Rico statute.

C. Criminal Prosecution of Pharmacists

Pharmacists are also subject to criminal prosecution for aiding in the diversion of prescription drugs.⁴²⁸ In addition, state regulatory agencies may impose civil fines or revoke their licenses for violating drug laws.⁴²⁹ One area of interest is the prescribing practices of Internet pharmacies.⁴³⁰ A recent federal case, *United States v. Tobin*,⁴³¹ involved the legality of Internet pharmacies which dispensed controlled substances (but apparently not OxyContin) without requiring customers to submit medical records or prescriptions.⁴³² From 2002 to 2005, one of the defendants owned and operated a company called Jive Network which sold prescription drugs through numerous Internet sites.⁴³³ During that period, Jive Network sold approximately 45 million Schedule III and Schedule IV pills, generating \$85 million or 80% of the company's revenue during that period.⁴³⁴

In 2008, the government charged the owner of the pharmacy, along with three physicians and a pharmacist, with distributing Schedule III and IV drugs without a prescription as well as with a host of other crimes.⁴³⁵ At trial, it was revealed that one of the medical doctors approved 40,000 orders for

⁴²⁵ *Id.* at 319.

⁴²⁶ *Id.* at 321.

⁴²⁷ *Id.* at 322.

⁴²⁸ Ken Lammers, Jr., *Rise of the Pills*, 15 UDC/DCSL L. REV. 91, 107 (2011).

⁴²⁹ See, e.g., Ala. State Bd. of Pharm. v. Holmes, 925 So. 2d 203, 207 (Ala. Civ. App. 2005); *Tewelde v. La. Bd. of Pharm.*, 93 So. 3d 801, 812-13 (La. Ct. App. 2012).

⁴³⁰ See Amy L. Caldwell, Note, *In the War on Prescription Drug Abuse, E-Pharmacies Are Making Doctor Shopping Irrelevant*, 7 HOUS. J. HEALTH L. & POL'Y 85, 104-08 (2006).

⁴³¹ 676 F.3d 1264 (11th Cir. 2012).

⁴³² *Id.* at 1270.

⁴³³ *Id.*

⁴³⁴ *Id.* at 1271.

⁴³⁵ *Id.* at 1271-72.

controlled substances and spent as little as six seconds reviewing individual customer orders.⁴³⁶ Another doctor approved more than 60,000 orders and spent as little as nine seconds on each order.⁴³⁷ The third physician was a bit more conscientious, spending about nineteen seconds per patient reviewing customer orders.⁴³⁸ The defendant pharmacist filled more than 21,000 of these prescriptions.⁴³⁹ The jury convicted all of the defendants and they appealed.⁴⁴⁰

On appeal, the defendants made two arguments. First, they contended that the CSA was unconstitutional because of vagueness.⁴⁴¹ In addition, they maintained that the rule of lenity should be applied to them.⁴⁴² In support of their “void for vagueness” claim, the defendants pointed out that the CSA did not explicitly prohibit the distribution of controlled substances over the Internet until 2008, when Congress enacted the Ryan Haight Online Pharmacy Consumer Protection Act⁴⁴³ as an amendment to the CSA.⁴⁴⁴ The defendants also argued that the CSA was unconstitutionally vague because it did not expressly state that an in-person patient visit was required to obtain a valid prescription over the Internet.⁴⁴⁵ The court was not persuaded by either of these arguments and upheld the constitutionality of the CSA.⁴⁴⁶

The defendants also tried to invoke the rule of lenity as a defense.⁴⁴⁷ The rule of lenity is intended to provide a fair warning of potential liability by “resolving ambiguity in a criminal statute as to apply it only to conduct clearly covered.”⁴⁴⁸ The defendants claimed that the CSA was ambiguous in two respects: (1) it did not clearly specify that it applied to distributions of controlled substances over the Internet; and (2) it was ambiguous about whether it required a physician to have an in-person patient visit before providing a prescription over the Internet.⁴⁴⁹ However, the appeals court rejected both of these arguments, declaring that the CSA criminalized the distribution of controlled substances without a valid prescription, regardless of

⁴³⁶ *Id.* at 1271.

⁴³⁷ *Id.*

⁴³⁸ *Id.*

⁴³⁹ *Id.*

⁴⁴⁰ *Id.* at 1272.

⁴⁴¹ *Id.* at 1278.

⁴⁴² *Id.* at 1273.

⁴⁴³ H.R. Res. 6353, 110th Cong. (2008) (enacted).

⁴⁴⁴ *Tobin*, 676 F.3d at 1278.

⁴⁴⁵ *Id.*

⁴⁴⁶ *Id.*

⁴⁴⁷ *Id.* at 1273.

⁴⁴⁸ *United States v. Lanier*, 520 U.S. 259, 266 (1997).

⁴⁴⁹ *Tobin*, 676 F.3d at 1274.

the method of distribution.⁴⁵⁰ As far as the defendant's second argument was concerned, the court concluded that the CSA deferred to state standards of professional practice, including state requirements with respect to prescriptions.⁴⁵¹ Finally, the court held that the government did not have to prove that the defendants acted "willfully"; rather, it was sufficient to show that they acted "knowingly," that is, that their actions were voluntary and intentional and not the result of an accident or mistake.⁴⁵² Accordingly, the court affirmed the defendants' convictions.⁴⁵³

V. ALTERNATIVES TO LITIGATION

A. *Problems with a Litigation-Oriented Strategy*

As the foregoing discussion suggests, civil litigation has not been very successful, particularly for former OxyContin users. As far as civil litigation is concerned, Purdue has pursued a policy of refusing to settle individual lawsuits and has prevailed at the summary judgment stage in most of them. One reason for the drug company's success is that many of these plaintiffs are drug abusers who generate little sympathy from trial court judges.⁴⁵⁴ In addition, Purdue has been able to shift much of the blame to "pill doctors" who have prescribed OxyContin in excessive quantities to their patients, arguing that their prescribing practices broke the chain of causation.⁴⁵⁵ In addition, Purdue has persuaded some courts that overriding OxyContin's time-release mechanism by chewing or crushing the pills constitutes misuse or alteration of the product.⁴⁵⁶ Finally, a number of these individual lawsuits were dismissed because the plaintiffs failed to comply with the statute of limitations.⁴⁵⁷ Class actions have also been ineffective, primarily because class representatives have been unable to get their putative classes certified. This failure is largely due to the inability of class representatives to meet the requirements of Rule 23(a).⁴⁵⁸

⁴⁵⁰ *Id.* at 1274–75.

⁴⁵¹ *Id.* at 1275–78.

⁴⁵² *Id.* at 1279–80.

⁴⁵³ *Id.* at 1310.

⁴⁵⁴ *See, e.g.,* Foister v. Purdue Pharma, L.P., 295 F. Supp. 2d 693, 703 (E.D. Ky. 2003); Price v. Purdue Pharma Co., 920 So. 2d 479, 486 (Miss. 2006).

⁴⁵⁵ *See, e.g.,* Koenig v. Purdue Pharma Co., 435 F. Supp. 2d 551, 555–56 (N.D. Tex. 2006).

⁴⁵⁶ *See, e.g.,* Labzda v. Purdue Pharma L.P., 292 F. Supp. 2d 1346, 1356 (S.D. Fla. 2003).

⁴⁵⁷ *See, e.g.,* Freund v. Purdue Pharma Co., No. 04-C-611, 2006 WL 482382, at *1 (E.D. Wis. Feb. 27, 2006); Franz v. Purdue Pharma Co., No. 05-CV-201-PB, 2006 WL 455998, at *2–3 (D.N.H. Feb. 22, 2006).

⁴⁵⁸ *See* Campbell v. Purdue Pharma, L.P., No. 1:02CV00163, 2004 WL 5840206, at *11 (E.D. Mo. June 25, 2004) (commonality, adequacy, and typicality); Harris v. Purdue Pharma, L.P., 218

On the other hand, Purdue has been forced to settle a number of *parens patriae* suits brought against it by state officials.⁴⁵⁹ In particular, Purdue paid the state of West Virginia \$10 million to settle negligent marketing and public nuisance for violating provisions of the CSA, and in some cases, for engaging in health care fraud and other illegal activities.⁴⁶⁰ These efforts have undoubtedly had some deterrent effect on those who contributed to the OxyContin abuse problem. Pill mills have been closed down and doctors have become more cautious about prescribing opioids to treat chronic pain. Indeed, some have complained about the chilling effect that high-profile arrests and prosecutions have had on those who engage in legitimate pain management practices.⁴⁶¹ Another unintended consequence of the DEA's campaign against prescription drug abuse is that it may have forced drug abusers to turn from prescription drugs like OxyContin to unregulated street drugs like cocaine or heroin.⁴⁶²

B. *Regulatory Alternatives to Litigation*

Commentators have suggested a number of regulatory measures to curb prescription drug abuse and some of these measures have been adopted in a few states.⁴⁶³ These include prescription monitoring programs, anti-doctor shopping legislation and unused prescription drug collection initiatives.⁴⁶⁴ Under prescription monitoring programs, a state agency maintains a database containing information about prescriptions of narcotic or other controlled substances. Physicians would be able to access this database to determine if a patient has obtained prescriptions from other doctors.⁴⁶⁵ The effectiveness of such monitoring programs can be increased even more if they can interact with similar databases in other states as well.⁴⁶⁶ Anti-doctor shopping laws are more

F.R.D. 590, 597 (S.D. Ohio 2003) (commonality); *Wethington v. Purdue Pharma L.P.*, 218 F.R.D. 577, 589 (S.D. Ohio 2003) (commonality); *Gevedon v. Purdue Pharma*, 212 F.R.D. 333, 338–41 (E.D. Ky. 2002) (adequacy, numerosity, and typicality).

⁴⁵⁹ See Prater, *supra* note 6, at 1424–25.

⁴⁶⁰ See Hoffmann, *supra* note 10, at 280–81.

⁴⁶¹ See Annemarie Daly Linares, Note, *Opioid Pseudoaddiction: A Casualty of the War on Drugs, Racism, Sexism and Opiophobia*, 15 QUINNIPIAC HEALTH L.J. 89, 95–97 (2011).

⁴⁶² See Jason Koebler, *Study: Heroin Abuse Increase May Be Due to Prescription Painkiller Crackdown*, U.S. NEWS & WORLD REP. (June 12, 2013), <http://www.usnews.com/news/articles/2013/06/12/study-heroin-abuse-increase-may-be-due-to-prescription-painkiller-crackdown>.

⁴⁶³ See Dutko, *supra* note 16, at 747–48.

⁴⁶⁴ See Woodworth, *supra* note 2, at 129–37 (describing these regulatory approaches).

⁴⁶⁵ *Id.* at 129.

⁴⁶⁶ *Id.* at 134–35.

controversial because they criminalize the act of obtaining prescriptions through fraud. However, it is interesting to observe that Florida has enacted such a law.⁴⁶⁷ A third approach is to establish a program to enable individuals to deposit unused prescription drugs as designated collection centers.⁴⁶⁸ The DEA currently maintains collection centers for this purpose.⁴⁶⁹ Hopefully, these “take back” programs will increase the number of unwanted drugs that are disposed of properly and not diverted to illegal uses.⁴⁷⁰

CONCLUSION

This Article has discussed the effectiveness of various forms of litigation as a tactic in fighting prescription drug abuse, especially as it relates to the overprescribing of OxyContin. Suits against Purdue by individual consumers have almost always failed because the company has successfully argued lack of causation, misuse, wrongful conduct and expiration of the statute of limitations. Class actions have also failed, primarily because class representatives have been unable to satisfy the Rule 23 requirements of numerosity, commonality, typicality and adequacy. *Parens patriae* suits against Purdue have been somewhat more successful, despite the weakness of their doctrinal foundations, primarily because the company has chosen to settle these suits in order to avoid the bad publicity and expense of protracted litigation. Nevertheless, the overall effectiveness of civil litigation in this area is highly questionable.

The criminal prosecution of Purdue forced it to change some of its promotion and marketing practices. In addition, the federal government’s prosecution of numerous doctors, pharmacists and other health care providers seems to have discouraged others from overprescribing OxyContin and other opioids. All of this seems to have reduced OxyContin abuse, at least for now. Nevertheless, these litigation-based efforts are not enough and they must be supplemented by other measures such as comprehensive prescription monitoring programs, anti-doctor shopping laws and prescription drug “take back” initiatives.

⁴⁶⁷ FLA. STAT. ANN. § 893.13(7)(a)(8)–(9) (West 2014).

⁴⁶⁸ See Woodworth, *supra* note 2, at 136.

⁴⁶⁹ See Ferrara, *supra* note 4, at 762–63.

⁴⁷⁰ See Toby K.L. Morgan, Note, *Down the Drain: Pharmaceutical Waste Disposal in the United States*, 22 FORDHAM ENVTL. L. REV. 393, 418–20 (2011).